

Standard Commercial
Prior Authorization Guidelines

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

Formulary Agents

Drug products that are listed in the Formulary as Prior Authorization (PA) require evaluation, per MedImpact Pharmacy and Therapeutics Committee guidelines, when the member presents a prescription to a network pharmacy. Each request will be reviewed on individual patient need. If the request does not meet the criteria established by the P & T Committee, the request will not be approved and alternative therapy will be recommended.

Non-Formulary Agents

Any product not found in the Formulary listing, or any Formulary updates published by MedImpact**,** shall be considered a Non-Formulary drug. Coverage for non-formulary agents may be applied for in advance. When a member gives a prescription order for a non-formulary drug to a pharmacist, the pharmacist will evaluate the patient's drug history and contact the physician to determine if there is a legitimate medical need for a non-formulary drug. Each request will be reviewed on individual patient need. The following basic criteria are used:

The use of Formulary Drug Products is contraindicated in the patient.
The patient has failed an appropriate trial of Formulary or related agents.
The choices available in the Drug Formulary are not suited for the present patient care need, and the drug selected is required for patient safety.
The use of a Formulary drug may provoke an underlying condition, which would be detrimental to patient care.

If the request does not meet the criteria established by the P & T Committee, the request will not be approved and alternative therapy will be recommended.

Obtaining Coverage

Coverage may be obtained by:

Faxing a completed **Medication Request Form** to MedImpact at (858) 790-7100.
Contacting MedImpact at (800) 788-2949 and providing all necessary information requested.

MedImpact will provide an authorization number, specific for the medical need, for all approved requests. Non-approved requests may be appealed. The prescriber must provide information to support the appeal on the basis of medical necessity.

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Effective: 7/1/2026

ABALOPARATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABALOPARATIDE	TYMLOS	44231		GPI-10 (3004400500)	

GUIDELINES FOR USE

Does the patient have a diagnosis of postmenopausal osteoporosis (ICD-10 M81.0, Group M80.0)?

If yes, continue to #2.
If no, continue to #4.

Is the patient at high risk for fractures defined as **ONE** of the following?
- History of osteoporotic (i.e., fragility, low trauma) fracture(s)
- Two or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as Synarel [nafarelin])
- No prior treatment for osteoporosis, AND a FRAX score of at least 20% for any major fracture OR at least 3% for hip fracture

If yes, continue to #6.
If no, continue to #3.

Does the patient meet **ONE** of the following criteria?
- The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
- The patient had a trial of, intolerance to, or a contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

If yes, continue to #6.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the request to increase bone density in a male patient with osteoporosis (ICD-10 M81.0, Group M80.0)?

If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ABALOPARATIDE

GUIDELINES FOR USE (CONTINUED)

Is the patient at high risk for fractures defined as **ONE** of the following?
- History of osteoporotic fracture (e.g., fragility, low trauma)
- Multiple risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, use of GnRH analogs such as Synarel [nafarelin])
- The patient has failed or is intolerant to other available osteoporosis therapy (e.g., Forteo [teriparatide], Prolia [denosumab], Fosamax [alendronate], Actonel [risedronate])

If yes, continue to #6.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Has the patient received a total of 24 months cumulative treatment with any parathyroid hormone therapy (e.g., Tymlos [abaloparatide], Forteo [teriparatide])?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve up to 24 months cumulative lifetime treatment by HICL or GPI-10 with a quantity limit of #1.56mL per 30 days.**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABALOPARATIDE (Tymlos)** requires the following rule(s) be met for approval:
The request is for ONE of the following:
- Postmenopausal osteoporosis (a type of bone condition)
- To increase bone density in a male patient with osteoporosis (a type of bone condition)

If you have postmenopausal osteoporosis, approval also requires:
- You have NOT received a total of 24 months or more of treatment with any parathyroid hormone therapy (such as Tymlos [abaloparatide], Forteo [teriparatide])

(Denial text continued on next page)

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ABALOPARATIDE

GUIDELINES FOR USE (CONTINUED)

You meet ONE of the following (a, b, or c):
- You are at high risk for fractures defined as ONE of the following:
  - You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
  - You have TWO or more risk factors for a fracture such as a history of multiple recent low trauma fractures, bone mineral density (BMD) T-score (a type of lab test) less than or equal to -2.5, corticosteroid use, or use of GnRH (gonadotropin-releasing hormone) analogs such as Synarel (nafarelin)
  - You have had no prior treatment for osteoporosis, AND you have a FRAX (Fracture Risk Assessment Tool: a type of test) score of at least 20% for any major fracture OR at least 3% for a hip fracture
- You are unable to use oral therapy due to upper gastrointestinal (GI: stomach and intestine) problems (unable to tolerate oral medication), lower GI problems (unable to absorb oral medications), or trouble remembering to take oral medications or cannot plan to use an oral bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate]) with other oral medications or in your daily routine
- You have tried, have an intolerance to (side effect), or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

If the request is to increase bone density in a male patient with osteoporosis, approval also requires:
- You have NOT received a total of 24 months or more of treatment with any parathyroid hormone therapy (such as Tymlos [abaloparatide], Forteo [teriparatide])
- You meet ONE of the following (a or b):
  - You are at high risk for fractures defined as ONE of the following:
    - You have a history of osteoporotic fracture (a type of complete or partial break in a bone, such as fragility [weakness] fracture, low trauma [injury] fracture)
    - You have multiple risk factors for fracture (such as a history of multiple recent low trauma fractures, bone mineral density [BMD] T-score [a type of lab test] less than or equal to -2.5, corticosteroid use, use of GnRH [gonadotropin-releasing hormone] analogs such as Synarel [nafarelin])
  - You have failed or are intolerant (side effect) to other available osteoporosis therapy (such as Forteo [teriparatide], Prolia [denosumab], Fosamax [alendronate], Actonel [risedronate])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ABALOPARATIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tymlos.

REFERENCES

Tymlos [Prescribing Information]. Boston, MA: Radius Health, Inc.; December 2023.

Created: 04/17
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABATACEPT/ MALTOSE	ORENCIA		26306	GPI-14 (66400010002120)	

NOTE: For requests for the SQ dosage form of Orencia, please see the ABATACEPT - SQ PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
- The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

If yes, continue to #2.
If no, continue to #3.

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?

The patient had a trial of or contraindication to TWO of the following preferred agents:

- Enbrel (etanercept)
- Adalimumab-ryvk/adalimumab-aaty
- Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
- Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
FIRST APPROVAL: Approve for 1 month with a quantity limit of #8 per 28 days.
SECOND APPROVAL: Approve for 5 months with a quantity limit of #4 per 28 days (start date is 3 days before the end date of the first approval).

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
  FIRST APPROVAL: Approve for 1 month with a quantity limit of #8 per 28 days.
  SECOND APPROVAL: Approve for 5 months with a quantity limit of #4 per 28 days (start date is 3 days before the end date of the first approval).

  If no, continue to #4.

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
FIRST APPROVAL: Approve for 1 month with a quantity limit of #8 per 28 days.
SECOND APPROVAL: Approve for 5 months with a quantity limit of #4 per 28 days (start date is 3 days before the end date of the first approval).

If no, continue to #5.

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

Is the request for prophylaxis of acute graft versus host disease (aGVHD) and the patient meets **ALL** of the following?
- The patient is 2 years of age or older
- The patient is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or one allele-mismatched unrelated-donor
- Orencia will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate
- Orencia will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of aGVHD prophylaxis

If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #16.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - IV (Orencia intravenous)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Prophylaxis (prevention) of acute graft versus host disease (aGVHD: a short-term type of immune disorder)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
- You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:

You are 18 years of age or older

Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)

You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:

Enbrel (etanercept)
Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
Otezla (apremilast)
Tremfya (guselkumab)
Skyrizi (risankizumab-rzaa)
Taltz (ixekizumab)
Bimzelx (bimekizumab-bkzx)
Sotyktu (deucravacitinib)
Adalimumab-ryvk/adalimumab-aaty
Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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ABATACEPT - IV

INITIAL CRITERIA (CONTINUED)

If the request is for prophylaxis of acute graft versus host disease, approval also requires:

You are 2 years of age or older

You are undergoing hematopoietic stem cell transplantation (HSCT: a type of cell transplantation) from a matched or one allele (version of a gene)-mismatched unrelated-donor

Orencia will be used in combination with a calcineurin inhibitor (such as cyclosporine or tacrolimus) and methotrexate

You will NOT use Orencia concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of acute graft versus host disease (a short-term type of immune disorder) prophylaxis (prevention)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ABATACEPT - IV

RENEWAL CRITERIA

NOTE: For the diagnosis of acute graft versus host disease (aGVHD), please refer to the Initial Criteria section.

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, continue to #2.
If no, continue to #3.

Does the patient meet **ONE** of the following criteria?
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
- The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per 28 days.**
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - IV

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?

The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

The patient had a trial of or contraindication to TWO of the following preferred agents:

Enbrel (etanercept)

Adalimumab-ryvk/adalimumab-aaty

Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per 28 days.**
If no, continue to #4.

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ABATACEPT - IV

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

The patient had a trial of or contraindication to TWO of the following preferred agents:

Enbrel (etanercept)
Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
Otezla (apremilast)
Tremfya (guselkumab)
Skyrizi (risankizumab-rzaa)
Taltz (ixekizumab)
Bimzelx (bimekizumab-bkzx)
Sotyktu (deucravacitinib)
Adalimumab-ryvk/adalimumab-aaty
Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per 28 days.**
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - IV

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABATACEPT - IV (Orencia intravenous)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Enbrel (etanercept)
    - Adalimumab-ryvk/adalimumab-aaty
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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ABATACEPT - IV

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:

You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:

Enbrel (etanercept)

Adalimumab-ryvk/adalimumab-aaty

Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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ABATACEPT - IV

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orencia IV.

REFERENCES

Orencia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2025.

Created: 05/05
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABATACEPT - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABATACEPT	ORENCIA, ORENCIA CLICKJECT	37825		GPI-14 (6640001000D520, 6640001000E510, 6640001000E515, 6640001000E520)	

NOTE: For requests for the IV dosage form of Orencia, please see the ABATACEPT - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
- The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

If yes, continue to #2.
If no, continue to #3.

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?

The patient had a trial of or contraindication to TWO of the following preferred agents:

Enbrel (etanercept)
Adalimumab-ryvk/adalimumab-aaty
Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve all formulations of the 125mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

If no, do not approve.
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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve all strengths and formulations for 6 months by GPID or GPI-14 as follows:**
  50mg/0.4mL: #1.6mL per 28 days.
  87.5mg/0.7mL: #2.8mL per 28 days.
  125mg/mL: #4mL per 28 days.

  If no, continue to #4.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

  If yes, continue to #5.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?

The patient is 2 to 5 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
- Enbrel (etanercept)
- Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])
- Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])

The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred agents:
- Enbrel (etanercept)
- Otezla (apremilast)
- Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])
- Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])

The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
- Enbrel (etanercept)
- Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
- Otezla (apremilast)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Taltz (ixekizumab)
- Bimzelx (bimekizumab-bkzx)
- Sotyktu (deucravacitinib)
- Adalimumab-ryvk/adalimumab-aaty
- Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
- Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve all strengths and formulations for 6 months by GPID or GPI-14 as follows:**
50mg/0.4mL: #1.6mL per 28 days.
87.5mg/0.7mL: #2.8mL per 28 days.
125mg/mL: #4mL per 28 days.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **ABATACEPT - SQ (Orencia subcutaneous)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard-of-care medication: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Enbrel (etanercept)
    - Adalimumab-ryvk/adalimumab-aaty
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

If you have psoriatic arthritis, approval also requires:
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
  - Enbrel (etanercept)
  - Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
- You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
- You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ABATACEPT - SQ

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, continue to #2.
If no, continue to #3.

Does the patient meet **ONE** of the following criteria?
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
- The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve all formulations of the 125mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve all strengths and formulations for 12 months by GPID or GPI-14 as follows:**
  50mg/0.4mL: #1.6mL per 28 days.
  87.5mg/0.7mL: #2.8mL per 28 days.
  125mg/mL: #4mL per 28 days.

  If no, continue to #4.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Orencia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

  If yes, continue to #5.
  If no, do not approve.
  DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?

The patient is 2 to 5 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
- Enbrel (etanercept)
- Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])
- Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])

The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred agents:
- Enbrel (etanercept)
- Otezla (apremilast)
- Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])
- Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])

The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
- Enbrel (etanercept)
- Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
- Otezla (apremilast)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Taltz (ixekizumab)
- Bimzelx (bimekizumab-bkzx)
- Sotyktu (deucravacitinib)
- Adalimumab-ryvk/adalimumab-aaty
- Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
- Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve all strengths & formulations for 12 months by GPID or GPI-14 as follows:**
50mg/0.4mL: #1.6mL per 28 days.
87.5mg/0.7mL: #2.8mL per 28 days.
125mg/mL: #4mL per 28 days.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: Our guideline named **ABATACEPT - SQ (Orencia subcutaneous)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    Enbrel (etanercept)
    Adalimumab-ryvk/adalimumab-aaty
    Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

(Renewal denial text continued on next page)

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

If you have psoriatic arthritis, renewal also requires:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Orencia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
- You meet ONE of the following:
  - You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
    - Enbrel (etanercept)
    - Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

(Renewal denial text continued on next page)

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
- Enbrel (etanercept)
- Otezla (apremilast)
- Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
- Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
- Enbrel (etanercept)
- Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
- Otezla (apremilast)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Taltz (ixekizumab)
- Bimzelx (bimekizumab-bkzx)
- Sotyktu (deucravacitinib)
- Adalimumab-ryvk/adalimumab-aaty
- Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
- Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ABATACEPT - SQ

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Orencia SQ.

REFERENCES
Orencia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2025.

Created: 11/11
Effective: 07/15/26 Client Approval: 07/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABEMACICLIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABEMACICLIB	VERZENIO	44537		GPI-10 (2153101000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of breast cancer (ICD-10 Group C50)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient's cancer in early stage and the patient meets **ALL** of the following criteria?
- The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive
- Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor [e.g., anastrozole, letrozole, exemestane]) for adjuvant treatment
- The patient is at high risk of recurrence

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
If no, continue to #3.

Is the patient's cancer advanced or metastatic **AND** the patient meets the following criterion?
- The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- Verzenio will be used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) as initial endocrine-based therapy
- Verzenio will be used in combination with fulvestrant (Faslodex) AND the patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)
- Verzenio will be used as monotherapy AND the patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen) and prior chemotherapy in the metastatic setting

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ABEMACICLIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABEMACICLIB (Verzenio)** requires the following rule(s) be met for approval:
You have breast cancer
If you have early breast cancer, approval also requires:
- Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, node-positive (cancer that has spread to the lymph nodes)
- Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor [such as letrozole, anastrozole, exemestane]) for adjuvant (add-on) treatment
- You are at high risk of recurrence (disease returning)

If you have advanced or metastatic breast cancer, approval also requires:
- Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
- You meet ONE of the following:
  - Verzenio will be used in combination with an aromatase inhibitor (such as letrozole, anastrozole, exemestane) as initial endocrine (hormone)-based therapy
  - Verzenio will be used in combination with fulvestrant (Faslodex); AND you have experienced disease progression following endocrine therapy (such as letrozole, anastrozole, tamoxifen)
  - Verzenio will be used as monotherapy (one medication treatment); AND you have experienced disease progression following endocrine therapy (such as letrozole, anastrozole, tamoxifen) as well as prior chemotherapy (drugs used to treat cancer) in the metastatic setting (cancer that has spread to other parts of the body)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Verzenio.

REFERENCES
Verzenio [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; February 2025.

Created: 10/17
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 04/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABIRATERONE ACETATE	ZYTIGA, ABIRTEGA, ABIRATERONE ACETATE	37571		GPI-10 (2140601020)	

GUIDELINES FOR USE

Does the patient have **ONE** of the following diagnoses?
Metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61)
Metastatic high-risk castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61)

If yes, continue to #2.
If no, continue to #5.

Will the requested medication be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
The patient had a bilateral orchiectomy
The patient has a castrate level of testosterone (less than 50 ng/dL)
The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
250mg: #8 per day.
500mg: #4 per day.

If no, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
250mg: #4 per day.
500mg: #2 per day.

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ABIRATERONE

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of metastatic androgen pathway modulation-naive or -sensitive (mAPMN/S) prostate cancer (ICD-10 C61, Z19.1) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The requested medication will be used in combination with Truqap (capivasertib) and prednisone
- The cancer is PTEN-deficient as detected by an FDA-authorized test

If yes, continue to #6.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient had a bilateral orchiectomy
- The patient has a castrate level of testosterone (less than 50 ng/dL)
- The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
250 mg: #4 per day.
500 mg: #2 per day.

If no, do not approve.

DENIAL TEXT: Our guideline named **ABIRATERONE (Zytiga, Abirtega)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
- Metastatic high-risk castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and may respond to testosterone lowering treatment)
- Metastatic androgen pathway modulation-naive or -sensitive (mAPMN/S) prostate cancer (cancer that has spread to other parts of the body and has not been treated with, or may respond to, testosterone-lowering treatment)

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ABIRATERONE

GUIDELINES FOR USE (CONTINUED)

If you have metastatic castration-resistant prostate cancer or metastatic high-risk castration-sensitive prostate cancer, approval also requires:
- The requested medication will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
- You meet ONE of the following:
  - You had a bilateral orchiectomy (both testicles have been surgically removed)
  - You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
  - The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If you have metastatic androgen pathway modulation-naive or -sensitive prostate cancer, approval also requires:
- You are 18 years of age or older
- The requested medication will be used in combination with Truqap (capivasertib) and prednisone
- Your prostate cancer is PTEN-deficient (loss of a type of gene) as detected by a Food and Drug Administration (FDA)-authorized test
- You meet ONE of the following:
  - You had a bilateral orchiectomy (both testicles have been surgically removed)
  - You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
  - The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zytiga.

REFERENCES
Zytiga [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; November 2024.
Truqap [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2026.

Created: 06/11
Effective: 07/08/26 Client Approval: 07/26 P&T Approval: 07/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABIRATERONE SUBMICRONIZED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABIRATERONE ACET, SUBMICRONIZED	YONSA	44946		GPI-10 (2140601025)	

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) and meet **ALL** of the following criteria?
- Yonsa will be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)
- The patient had a trial of or contraindication to the preferred agent: Zytiga (abiraterone acetate)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient had a bilateral orchiectomy
- The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
- Yonsa will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**

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ABIRATERONE SUBMICRONIZED

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABIRATERONE SUBMICRONIZED (Yonsa)** requires the following rule(s) be met for approval:

- You have metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
- Yonsa will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Zytiga (abiraterone acetate)
- You meet ONE of the following:
  - You had a bilateral orchiectomy (both testicles have been surgically removed)
  - You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
  - Yonsa will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yonsa.

REFERENCES

Yonsa [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc.; March 2022.

Created: 03/23
Effective: 02/12/26 Client Approval: 02/26 P&T Approval: 07/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABROCITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABROCITINIB	CIBINQO	47767		GPI-10 (9027200500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of refractory, moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?

The patient is 12 years of age or older

Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist

The patient has atopic dermatitis involving at least 10% of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

The patient had a trial of or contraindication to THREE of the following preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm), Ebglyss (lebrikizumab- lbkz), Nemluvio (nemolizumab-ilto)

Cibinqo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD
[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ABROCITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for approval:

You have refractory (did not respond to treatment), moderate to severe atopic dermatitis (AD: a type of skin condition)

You are 12 years of age or older

Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)

You have atopic dermatitis (a type of skin condition) involving at least 10 percent of body surface area (BSA) OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)

You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto)

You will NOT use Cibinqo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ABROCITINIB

RENEWAL CRITERIA

Does the patient have a diagnosis of refractory, moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?

The patient has shown improvement while on Cibinqo

The patient had a trial of or contraindication to THREE of the following preferred agents: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm), Ebglyss (lebrikizumab- lbkz), Nemluvio (nemolizumab-ilto)

Cibinqo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: Our guideline named **ABROCITINIB (Cibinqo)** requires the following rule(s) be met for renewal:

You have refractory (did not respond to treatment), moderate to severe atopic dermatitis (AD: a type of skin condition)

You have shown improvement while on Cibinqo

You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Dupixent (dupilumab), Rinvoq (upadacitinib), Adbry (tralokinumab-ldrm), Ebglyss (lebrikizumab-lbkz), Nemluvio (nemolizumab-ilto)

You will NOT use Cibinqo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cibinqo.

REFERENCES

Cibinqo [Prescribing Information]. New York, NY: Pfizer Inc.; December 2023.

Created: 02/22
Effective: 07/15/26 DMC Approval: 06/29/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACALABRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ACALABRUTINIB	CALQUENCE	44607		GPI-10 (2153210300)	
ACALABRUTINIB MALEATE	CALQUENCE	48182		GPI-10 (2153210350)	

GUIDELINES FOR USE

Does the patient have a diagnosis of mantle cell lymphoma (MCL) (ICD-10 Group C83.1) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, continue to #4.

Is the patient previously untreated and meets **ALL** of the following criteria?
Calquence is being used in combination with bendamustine and rituximab
The patient is ineligible for autologous hematopoietic stem cell transplantation (HSCT)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
If no, continue to #3.

Has the patient received at least one prior therapy (e.g., rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone [R-CHOP])?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
If no, continue to #5.

Is the request for a currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document? (see FDA website for approved drugs indications: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ACALABRUTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACALABRUTINIB (Calquence)** requires the following rules be met for approval:
You have ONE of the following:
- Mantle cell lymphoma (MCL: a type of blood cancer)
- Chronic lymphocytic leukemia (CLL: a type of blood cancer)
- Small lymphocytic lymphoma (SLL: a type of blood cancer)
- A currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document

If you have untreated mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- Calquence will be used in combination with bendamustine and rituximab
- You are NOT eligible for autologous hematopoietic stem cell transplantation (HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)

If you have previously treated mantle cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have received at least one prior therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])

If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
- You are 18 years of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Calquence.

REFERENCES

Calquence [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; January 2025.

Created: 02/18
Effective: 02/09/26 Client Approval: 02/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACNE AGE RESTRICTION OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAPALENE	DIFFERIN, ADAPALENE		28403	GPI-14 (90050003004110)	
TRETINOIN	ALTRENO		45194	GPI-14 (90050030004130)	
TAZAROTENE	TAZAROTENE, TAZORAC		29221 29222 85362	GPI-14 (90250070004020, 90250070004030, 90250070003720)	
TRETINOIN MICROSPHERES	RETIN-A MICRO, RETIN-A MICRO PUMP, TRETINOIN MICROSPHERES	32888		GPI-10 (9005003020)	
TRIFAROTENE	AKLIEF	46048		GPI-10 (9005003500)	

GUIDELINES FOR USE

Is the claim denying for an age limit, as noted in the POS reject message?

If yes, continue to #2.
If no, guideline does not apply.

Is the request for a cosmetic indication (e.g., melasma, photoaging, or wrinkles)?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
If no, continue to #3.

Has the patient had a trial of **TWO** low cost, clinical standard of care generic agents (e.g., adapalene cream or gel, tretinoin cream or gel, adapalene/benzoyl peroxide gel)?

If yes, **approve the requested agent for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACNE AGE RESTRICTION OVERRIDE** requires the following rule(s) be met for approval:
Your request is NOT for a cosmetic indication (not for improving appearance, such as for melasma [freckle-like spots on the skin], photoaging [sun-damaged skin], wrinkles)
You had a trial of TWO low cost, clinical standard of care generic medications (such as adapalene lotion, cream or gel, tretinoin cream or gel, adapalene/benzoyl peroxide gel)

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ACNE AGE RESTRICTION OVERRIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for agents in this guideline

REFERENCES

Differin [Prescribing Information]. Dallas, TX: Galderma laboratories, L.P; April 2023.
Altreno [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; August 2018.
Retin-A [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; March 2024.
Aklief [Prescribing Information]. Dallas, TX: Galderma laboratories, L.P; January 2022.
Differin [Prescribing Information]. Dallas, TX: Galderma laboratories, L.P; April 2023.
Tazorac [Prescribing Information]. Medison, NJ: Allergan, Inc.; April 2018.

Created: 08/11
Effective: 09/23/26 Client Approval: 09/26 P&T Approval: 07/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ACORAMIDIS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ACORAMIDIS HCL	ATTRUBY	50022		GPI-10 (4055001030)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or variant transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
- The patient has New York Heart Association (NYHA) Class I, II, or III heart failure
- Attruby will NOT be used concurrently with a transthyretin stabilizer (tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of ATTR-CM

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's diagnosis confirmed by **ONE** of the following?
- A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP *(**Note:** Strongly positive defined as Grade 2 or 3 uptake using the Perugini Grade 1-3 scoring system)*
- A biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence AND chemical typing to confirm presence of transthyretin (TTR) protein

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ACORAMIDIS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACORAMIDIS (Attruby)** requires the following rule(s) be met for approval:
You have cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
You have New York Heart Association (NYHA) Class I, II, or III heart failure (classification of heart failure symptoms)
You will NOT use Attruby concurrently (at the same time) with a transthyretin stabilizer (tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)
Your diagnosis is confirmed by ONE of the following:
- A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging test) (Note: Strongly positive defined as Grade 2 or 3 uptake using the Perugini Grade 1-3 scoring system)
- A biopsy of tissue of the affected organ(s) (removal of cells or tissue from the body for examination) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein

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ACORAMIDIS

RENEWAL CRITERIA

Does the patient have a diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or variant transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) **AND** meet the following criterion?
Attruby will NOT be used concurrently with a transthyretin stabilizer (tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of ATTR-CM

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ACORAMIDIS (Attruby)** requires the following rule(s) be met for renewal:
You have cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
You will NOT use Attruby concurrently (at the same time) with a transthyretin stabilizer (tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of cardiomyopathy of wild-type or variant transthyretin- mediated amyloidosis (heart disease caused by a build-up of a type of protein)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Attruby.

REFERENCES

Attruby [Prescribing Information]. Palo Alto, CA: BridgeBio Pharma Inc.; November 2024.

Created: 12/24
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAGRASIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAGRASIB	KRAZATI	48522		GPI-10 (2153241000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer has a KRAS G12C mutation as determined by an FDA-approved test
The patient has received at least one prior systemic therapy

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
If no, continue to #2.

Does the patient have a diagnosis of locally advanced or metastatic colorectal cancer (CRC) (ICD- 10 C19) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer has a KRAS G12C mutation as determined by an FDA-approved test
Krazati will be used in combination with Erbitux (cetuximab)
The patient has received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADAGRASIB (Krazati)** requires the following rule(s) be met for approval:
You have ONE of the following:
Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
Locally advanced or metastatic colorectal cancer (CRC: a type of digestive tract cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
You are 18 years of age or older
Your cancer has a KRAS G12C mutation (a type of abnormal gene) as determined by a Food and Drug Administration (FDA)-approved test
You have received at least one prior systemic therapy
(Denial text continued on next page)

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ADAGRASIB

GUIDELINES FOR USE (CONTINUED)

If you have locally advanced or metastatic colorectal cancer, approval also requires:

You are 18 years of age or older
Your cancer has a KRAS G12C mutation (a type of abnormal gene) as determined by a Food and Drug Administration (FDA)-approved test
Krazati will be used in combination with Erbitux (cetuximab)
You have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (drugs used to treat cancer)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Krazati.

REFERENCES

Krazati [Prescribing Information]. San Diego, CA: Mirati Therapeutics, Inc.; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 01/23
Client Approval: 07/24
P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB-AATY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB-AATY	ADALIMUMAB-AATY	48955		GPI-10 (6627001503)	GENERIC ONLY

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (NOTE: Enter a proactive PA for adalimumab-ryvk for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days).**

If no, continue to #2.

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (NOTE: Enter a proactive PA for adalimumab-ryvk for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days).**

If no, continue to #3.

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ADALIMUMAB-AATY

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (NOTE: Enter a proactive PA for adalimumab-ryvk for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days).**

If no, continue to #4.

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
- The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (NOTE: Enter a proactive PA for adalimumab-ryvk for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days).**

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, continue to #6.
If no, continue to #8.

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INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant and PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

If yes, continue to #7.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient was previously stable on another biologic and is switching to adalimumab-aaty
- The patient has psoriasis covering 3 percent or more of body surface area (BSA)
- The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #4 per 28 days.)**
(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for adalimumab-ryvk.)

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB-AATY

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
The patient is 6 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist
Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #3 per 28 days.)**
(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for adalimumab-ryvk.)

If no, continue to #9.

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
The patient is 5 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist
Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 per 28 days. (PAC NOTE: Enter a proactive PA for adalimumab-ryvk for 6 months by HICL or GPI-10 with a quantity limit of #4 per 28 days).**

If no, continue to #10.

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ADALIMUMAB-AATY

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
The patient is 12 years of age or older
Therapy is prescribed by or in consultation with a dermatologist
Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #4 per 28 days. (PAC NOTE: Enter a proactive PA for adalimumab-ryvk for 4 months by HICL or GPI-10 with a quantity limit of #4 per 28 days).**

If no, continue to #11.

Does the patient have a diagnosis of non-infectious intermediate uveitis or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
Therapy is prescribed by or in consultation with an ophthalmologist
The patient does NOT have isolated anterior uveitis
Adalimumab-aaty will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #4 per 28 days.)**
(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for adalimumab-ryvk.)

If no, continue to #12.

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ADALIMUMAB-AATY

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of non-infectious posterior uveitis and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient does NOT have isolated anterior uveitis
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis
- The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: a glucocorticoid (e.g., methylprednisolone, prednisone), a systemic antimetabolite (e.g., methotrexate, cyclosporine, azathioprine, tacrolimus, mycophenolate mofetil)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #4 per 28 days.)**
(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for adalimumab-ryvk.)

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-AATY (Yuflyma)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

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ADALIMUMAB-AATY

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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ADALIMUMAB-AATY

INITIAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
- You meet ONE of the following:
  - You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to adalimumab-aaty
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

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ADALIMUMAB-AATY

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin disorder)

If you have non-infectious intermediate, posterior, or panuveitis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
- You do NOT have isolated anterior uveitis (a different type of eye inflammation)
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
- If you have non-infectious posterior uveitis (a type of eye condition), approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a glucocorticoid (such as methylprednisolone, prednisone), a systemic antimetabolite (such as methotrexate, cyclosporine, azathioprine, tacrolimus, mycophenolate mofetil)

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ADALIMUMAB-AATY

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per 28 days**.
If no, continue to #2.

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, continue to #4.

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ADALIMUMAB-AATY

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, continue to #5.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, continue to #6.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, continue to #7.

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
If no, continue to #8.

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ADALIMUMAB-AATY

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
- The patient has shown improvement in HS symptoms
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
If no, continue to #9.

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
- Adalimumab-aaty will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis
- The patient has maintained quiescence OR has improved or maintained symptomatic improvement (e.g., eye redness, pain, photophobia, floaters, blurred vision)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-AATY

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-AATY (Yuflyma)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:

- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

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ADALIMUMAB-AATY

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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ADALIMUMAB-AATY

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You have shown improvement in your hidradenitis suppurativa symptoms
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

If you have non-infectious intermediate, posterior, and panuveitis, renewal also requires:
- You will NOT use adalimumab-aaty concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
- You have maintained quiescence (inactive disease) OR have improved or maintained symptomatic improvement (such as eye redness, pain, photophobia [sensitivity to light], floaters, blurred vision)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yuflyma and Humira.

REFERENCES

Yuflyma [Prescribing Information]. Jersey City, NJ: CELLTRION USA, Inc.; October 2025.
Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; December 2025.

Created: 05/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB-ADAZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB-ADAZ	ADALIMUMAB-ADAZ		53885	GPI-14 (6627001504E508)	GENERIC ONLY

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #0.2mL per 28 days.**
If no, continue to #2.

Does the patient have a diagnosis of non-infectious intermediate uveitis or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient does NOT have isolated anterior uveitis
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #0.2mL per 28 days.**
If no, continue to #3.

Does the patient have a diagnosis of non-infectious posterior uveitis and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient does NOT have isolated anterior uveitis
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis
- The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: a glucocorticoid (e.g., methylprednisolone, prednisone), a systemic antimetabolite (e.g., methotrexate, cyclosporine, azathioprine, tacrolimus, mycophenolate mofetil)

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #0.2mL per 28 days.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB-ADAZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-ADAZ** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

If you have non-infectious intermediate, posterior, or panuveitis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
- You do NOT have isolated anterior uveitis (a different type of eye inflammation)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
- If you have non-infectious posterior uveitis (a type of eye condition), approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a glucocorticoid (such as methylprednisolone, prednisone), a systemic antimetabolite (such as methotrexate, cyclosporine, azathioprine, tacrolimus, mycophenolate mofetil)

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.2mL per 28 days.**
If no, continue to #2.

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis
- The patient has maintained quiescence OR has improved or maintained symptomatic improvement (e.g., eye redness, pain, photophobia, floaters, blurred vision)

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.2mL per 28 days.**
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-ADAZ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-ADAZ** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

If you have non-infectious intermediate, posterior, or panuveitis, renewal also requires:
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
- You have maintained quiescence (inactive disease) OR have improved or maintained symptomatic improvement (such as eye redness, pain, photophobia [sensitivity to light], floaters, blurred vision)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Hyrimoz and Humira.

REFERENCES
Hyrimoz [Prescribing Information]. Princeton, NJ: Sandoz Inc.; June 2024.
Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; December 2025.

Created: 11/23
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADALIMUMAB-RYVK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADALIMUMAB-RYVK	ADALIMUMAB-RYVK	49415		GPI-10 (6627001540)	GENERIC ONLY

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (NOTE: Enter a proactive PA for adalimumab-aaty for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days).**

If no, continue to #2.

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (NOTE: Enter a proactive PA for adalimumab-aaty for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days).**

If no, continue to #3.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (NOTE: Enter a proactive PA for adalimumab-aaty for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days).**

If no, continue to #4.

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
- The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (NOTE: Enter a proactive PA for adalimumab-aaty for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days).**

If no, continue to #5.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, continue to #6.
If no, continue to #8.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant and PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Remicade [infliximab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

If yes, continue to #7.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient was previously stable on another biologic and is switching to adalimumab-ryvk
- The patient has psoriasis covering 3 percent or more of body surface area (BSA)
- The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #4 per 28 days.)**
(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for adalimumab-aaty.)

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
The patient is 6 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist
Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #3 per 28 days.)**
(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for adalimumab-aaty.)

If no, continue to #9.

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
The patient is 5 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist
Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 per 28 days. (PAC NOTE: Enter a proactive PA for adalimumab-aaty for 6 months by HICL or GPI-10 with a quantity limit of #4 per 28 days.)**

If no, continue to #10.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #4 per 28 days. (PAC NOTE: Enter a proactive PA for adalimumab-aaty for 4 months by HICL or GPI-10 with a quantity limit of #4 per 28 days)**

If no, continue to #11.

Does the patient have a diagnosis of non-infectious intermediate uveitis or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient does NOT have isolated anterior uveitis
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #4 per 28 days.)**
(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for adalimumab-aaty.)

If no, continue to #12.

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of non-infectious posterior uveitis and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient does NOT have isolated anterior uveitis
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis
- The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: a glucocorticoid (e.g., methylprednisolone, prednisone), a systemic antimetabolite (e.g., methotrexate, cyclosporine, azathioprine, tacrolimus, mycophenolate mofetil)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #4 per 28 days.)**
(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for adalimumab-aaty.)

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-RYVK (Simlandi)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

If you have psoriatic arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
- You meet ONE of the following:
  - You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Remicade [infliximab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to adalimumab-ryvk
  - You have psoriasis covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

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ADALIMUMAB-RYVK

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

If you have moderate to severe ulcerative colitis, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 12 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

If you have non-infectious intermediate, posterior, or panuveitis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor)
- You do NOT have isolated anterior uveitis (a different type of eye inflammation)
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
- If you have non-infectious posterior uveitis (a type of eye condition), approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a glucocorticoid (such as methylprednisolone, prednisone), a systemic antimetabolite (such as methotrexate, cyclosporine, azathioprine, tacrolimus, mycophenolate mofetil)

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ADALIMUMAB-RYVK

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per 28 days**.
If no, continue to #2.

Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Enbrel [etanercept]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, continue to #3.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, continue to #4.

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, continue to #5.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, continue to #6.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, continue to #7.

Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Remicade [infliximab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
If no, continue to #8.

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
- The patient has shown improvement in HS symptoms
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic (e.g., Cosentyx [secukinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
If no, continue to #9.

Does the patient have a diagnosis of non-infectious intermediate, posterior, or panuveitis (ICD-10 Group H44.11) and meet **ALL** of the following criteria?
- Adalimumab-ryvk will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of uveitis
- The patient has maintained quiescence OR has improved or maintained symptomatic improvement (e.g., eye redness, pain, photophobia, floaters, blurred vision)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADALIMUMAB-RYVK (Simlandi)** requires the following rule(s) be met for renewal:

You have ONE of the following:

- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Moderate to severe polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)
- Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)
- Non-infectious intermediate, posterior, or panuveitis (a type of eye condition)

If you have moderate to severe rheumatoid arthritis, renewal also requires:

- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy

If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Enbrel [etanercept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

(Renewal denial text continued on next page)

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

If you have moderate to severe ulcerative colitis, renewal also requires:
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Remicade [infliximab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

(Renewal denial text continued on next page)

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ADALIMUMAB-RYVK

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
- You have shown improvement in your hidradenitis suppurativa symptoms
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic (such as Cosentyx [secukinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

If you have non-infectious intermediate, posterior, or panuveitis, renewal also requires:
- You will NOT use adalimumab-ryvk concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of uveitis (a type of eye condition)
- You have maintained quiescence (inactive disease) OR have improved or maintained symptomatic improvement (such as eye redness, pain, photophobia [sensitivity to light], floaters, blurred vision)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Simlandi and Humira.

REFERENCES

Simlandi [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; August 2024.
Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc.; December 2025.

Created: 08/24
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAMTS13 RECOMBINANT-KRHN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAMTS13, RECOMBINANT-KRHN	ADZYNMA	49300		GPI-10 (8518200530)	

GUIDELINES FOR USE

Does the patient have a diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) (ICD- 10 D69.42)?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADAMTS13 RECOMBINANT-KRHN (Adzynma)** requires the following rule(s) be met for approval:
You have congenital thrombotic thrombocytopenic purpura (cTTP: a type of blood disorder)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adzynma.

REFERENCES

Adzynma [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; June 2024.

Created: 12/23
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAPALENE-BENZOYL-CLINDAMYCIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADAPALENE/BENZOYL/ CLINDAMYCIN	CABTREO	46076		GPI-10 (9005990302)	BRAND = CABTREO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of acne vulgaris (ICD-10 L70.0) and meet **ALL** of the following criteria?

The patient is 12 years of age or older

Cabtreo will NOT be used concurrently with other single source brand acne agents (e.g., Aklief, Winlevi)

The patient had a trial of or contraindication to ONE clinical standard of care agent in EACH of the following categories: a benzoyl peroxide product, a topical retinoid (e.g., adapalene, tretinoin), a topical antibiotic (e.g., clindamycin, erythromycin)

If yes, **approve for 12 weeks by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADAPALENE-BENZOYL-CLINDAMYCIN (Cabtreo)** requires the following rule(s) be met for approval:

You have acne vulgaris (a type of skin condition usually called pimples)

You are 12 years of age or older

Cabtreo will NOT be used at the same time with other acne therapies that are only available as brand name (such as Aklief, Winlevi)

You have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care medication in EACH of the following categories:
- Benzoyl peroxide product
- Topical retinoid (such as adapalene, tretinoin)
- Topical antibiotic (such as clindamycin, erythromycin)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADAPALENE-BENZOYL-CLINDAMYCIN

RENEWAL CRITERIA

Does the patient have a diagnosis of acne vulgaris (ICD-10 L70.0) and meet **ALL** of the following criteria?
The patient has shown improvement in acne symptoms
Cabtreo will NOT be used concurrently with other single source brand acne agents (e.g., Aklief, Winlevi)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADAPALENE-BENZOYL-CLINDAMYCIN (Cabtreo)** requires the following rule(s) be met for renewal:
You have acne vulgaris (a type of skin condition usually called pimples)
You have shown improvement in your acne symptoms (the treatment is working)
Cabtreo will NOT be used at the same time with other acne therapies that are only available as brand name (such as Aklief, Winlevi)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cabtreo.

REFERENCES

Cabtreo [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; March 2025.

Created: 11/23
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADO-TRASTUZUMAB EMTANSINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADO-TRASTUZUMAB EMTANSINE	KADCYLA	40046		GPI-10 (2135507030)	

GUIDELINES FOR USE

Does the patient have a diagnosis of breast cancer (ICD-10 Group C50)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient's cancer metastatic and the patient meets **ALL** of the following criteria?
The patient's cancer is HER2-positive
The patient has previously received trastuzumab and a taxane (e.g., docetaxel, paclitaxel)
The patient has received prior therapy for metastatic disease OR has developed disease recurrence during or within 6 months of completing adjuvant therapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Is the patient's cancer in early stage and the patient meets **ALL** of the following criteria?
The patient's cancer is HER2-positive
The patient has residual invasive disease after neoadjuvant taxane (e.g., docetaxel, paclitaxel) and trastuzumab-based treatment

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ADO-TRASTUZUMAB EMTANSINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADO-TRASTUZUMAB EMTANSINE (Kadcyla)** requires the following rule(s) be met for approval:
You have breast cancer
If you have metastatic breast cancer (cancer that has spread to other parts of the body), approval also requires:
- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
- You have previously received trastuzumab and a taxane (such as docetaxel, paclitaxel)
- You have received prior therapy for metastatic disease OR have developed disease recurrence (disease has returned) during or within 6 months of completing adjuvant (add-on) therapy

If you have early breast cancer (cancer has not spread to other parts of the body), approval also requires:
- Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
- You have residual (remaining) invasive disease after neoadjuvant (given before main treatment) taxane and trastuzumab-based treatment (types of cancer treatment)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Kadcyla.

REFERENCES
Kadcyla [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2022.

Created: 03/13
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 07/19

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ADUCANUMAB-AVWA (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ADUCANUMAB-AVWA	ADUHELM	47421		GPI-10 (6205051010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of Alzheimer's disease (ICD-10 Group G30) and meet **ALL** of the following criteria?
- The patient has mild cognitive impairment or mild dementia
- Therapy is prescribed by or in consultation with a neurologist, geriatrician, or psychiatrist
- The patient has the presence of amyloid-beta plaques
- The patient has a Clinical Dementia Rating (CDR) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE) score of 24-30
- The patient had a baseline brain MRI within one year prior to treatment
- The patient does NOT have a history of a clotting disorder
- The patient is participating in an FDA/NIH approved clinical trial
- The patient is NOT concurrently using any anticoagulant or antiplatelet therapy (e.g., Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less

If yes, **approve for 6 months by HICL or GPI-10 for #1 fill per 21 days.**
If no, do not approve.
INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADUCANUMAB-AVWA (Aduhelm)** requires the following rule(s) be met for approval:
- You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
- You have mild cognitive impairment (decreased ability to process, understand, store and remember information) or mild dementia (a type of memory disorder) due to Alzheimer's disease
- Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), geriatrician (a doctor who specializes in the health care of elderly individuals), or psychiatrist (a type of mental health doctor)
- You have the presence of amyloid-beta plaques (an indicator of Alzheimer's disease)
- You have a Clinical Dementia Rating (CDR: a tool for evaluating memory loss) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE: a test used to evaluate memory, thinking, and understanding) score of 24 to 30

(Initial denial text continued on next page)

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ADUCANUMAB-AVWA (NSA)

INITIAL CRITERIA (CONTINUED)

You have had a baseline brain MRI (magnetic resonance imaging) within one year prior to treatment
You do NOT have a history of a clotting disorder (condition that interferes with the blood's ability to clot)
You are participating in an FDA (Federal Drug Administration)/NIH (National Institute of Health) approved clinical trial
You are NOT concurrently (at the same time) using any anticoagulant or antiplatelet therapy (such as Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADUCANUMAB-AVWA (NSA)

RENEWAL CRITERIA

Does the patient have a diagnosis of Alzheimer's disease (ICD-10 Group G30) and meet **ALL** of the following criteria?
- The patient has mild cognitive impairment or mild dementia
- The patient's cognitive decline has slowed or stopped
- The patient is NOT experiencing any severe, unstable, or symptomatic amyloid-related imaging abnormalities (ARIA)
- The patient is NOT concurrently using any anticoagulant or antiplatelet therapy (e.g., Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less

If yes, **approve for 12 months by HICL or GPI-10 for #1 fill per 21 days.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ADUCANUMAB-AVWA (Aduhelm)** requires the following rule(s) be met for renewal:
- You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
- You have mild cognitive impairment (decreased ability to process, understand, store and remember information) or mild dementia (a type of memory disorder) due to Alzheimer's disease
- Your cognitive decline has slowed or stopped
- You are NOT experiencing any severe, unstable, or symptomatic amyloid-related imaging abnormalities (ARIA: abnormal differences seen on magnetic resonance imaging [MRI: a type of imaging] of the brain)
- You are NOT concurrently (at the same time) using any anticoagulant or antiplatelet therapy, (such as Xarelto [rivaroxaban], Pradaxa [dabigatran], Plavix [clopidogrel], Effient [prasugrel]), except for aspirin at 81mg daily or less

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ADUCANUMAB-AVWA (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aduhelm.

REFERENCES

Aduhelm [Prescribing Information]. Cambridge, MA: Biogen, Inc.; August 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/24

Created: 06/21
Client Approval: 06/24

P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AFAMELANOTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AFAMELANOTIDE ACETATE	SCENESSE	46203		GPI-10 (9092201010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of erythropoietic protoporphyria (EPP) (ICD-10 E80.0, E80.29) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has a history of phototoxic reactions
Scenesse will be used to increase pain free light exposure
Therapy is prescribed by or in consultation with a dermatologist or hematologist
The patient has an elevated total erythrocyte protoporphyrin that is greater than 3 times the upper limit of normal (ULN) AND the majority of protoporphyrin is metal-free

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 2 months.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFAMELANOTIDE (Scenesse)** requires the following rule(s) be met for approval:
You have erythropoietic protoporphyria (EPP: a rare disorder that makes exposure to light extremely painful)
You are 18 years of age or older
You have a history of phototoxic reactions (damage to the skin)
Scenesse will be used to increase pain free light exposure
Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor) or hematologist (a type of blood doctor)
You have an elevated (higher than normal) total erythrocyte protoporphyrin (a type of lab test) that is greater than 3 times the upper limit of normal (ULN) AND the majority of protoporphyrin (a type of substance in the body) is metal-free

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AFAMELANOTIDE

RENEWAL CRITERIA

Does the patient have a diagnosis of erythropoietic protoporphyria (EPP) (ICD-10 E80.0, E80.29)
AND meet the following criterion?
The patient has shown a positive clinical response in phototoxic reactions

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 2 months.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFAMELANOTIDE (Scenesse)** requires the following rule(s) be met for renewal:
You have erythropoietic protoporphyria (EPP: a rare disorder that makes exposure to light extremely painful)
You have shown a positive clinical response in phototoxic reactions (damage to the skin)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Scenesse.

REFERENCES

Scenesse [Prescribing Information] Burlingame, CA: Clinuvel, Inc.; August 2024.

Created: 05/20
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AFATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AFATINIB DIMALEATE	GILOTRIF	40478		GPI-10 (2136000610)	

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
- The patient's tumor has a non-resistant epidermal growth factor receptor (EGFR) mutation as detected by an FDA-approved test
- Gilotrif will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, continue to #2.

Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
- The patient's disease has progressed after platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFATINIB (Gilotrif)** requires the following rule(s) be met for approval:
You have non-small cell lung cancer (NSCLC: type of lung cancer)

If you have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body), approval also requires:
- Your tumor has a non-resistant epidermal growth factor receptor (EGFR: type of protein) mutation as shown by an FDA (Food and Drug Administration)-approved test
- You will NOT use Gilotrif concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

If you have metastatic squamous non-small cell lung cancer (cancer began in the squamous cells of the lung and has spread to other parts of the body), approval also requires:
- Your disease has progressed (worsened) after using platinum-based chemotherapy (cisplatin, carboplatin, oxaliplatin)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AFATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gilotrif.

REFERENCES

Gilotrif [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; April 2022.

Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AFICAMTEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AFICAMTEN	MYQORZO	51071		GPI-10 (4019000500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) (ICD-10 I42.1) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist
- The patient has New York Heart Association (NYHA) functional class II or III
- The patient has a peak left ventricular outflow tract (LVOT) gradient of at least 50 mmHg at rest or with provocation
- Myqorzo will NOT be used concurrently with another myosin inhibitor (e.g., Camzyos [mavacamten]) for the treatment of hypertrophic cardiomyopathy
- The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: a beta-blocker (e.g., metoprolol, carvedilol), a non-dihydropyridine calcium channel blocker (e.g., verapamil, diltiazem)
- The patient had a trial of or contraindication to the preferred agent: Camzyos (mavacamten)

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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AFICAMTEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFICAMTEN (Myqorzo)** requires the following rule(s) be met for approval:
You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
You have New York Heart Association (NYHA) functional class II or III (a way to classify the severity of symptoms)
You have a peak left ventricular outflow tract (LVOT) gradient (evaluates the severity of disease) of at least 50 mmHg at rest or with provocation (a type of technique to evaluate how the heart performs under stress)
You will NOT use Myqorzo concurrently (at the same time) with another myosin inhibitor (such as Camzyos [mavacamten]) for the treatment of hypertrophic cardiomyopathy (a type of heart condition)
You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a beta-blocker (such as metoprolol, carvedilol), a non- dihydropyridine calcium channel blocker (such as verapamil, diltiazem)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Camzyos (mavacamten)

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AFICAMTEN

RENEWAL CRITERIA

Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) (ICD-10 I42.1) and meet **ALL** of the following criteria?
- The patient has experienced continued clinical benefit (e.g., reduction of symptoms, NYHA classification improvement)
- Myqorzo will NOT be used concurrently with another myosin inhibitor (e.g., Camzyos [mavacamten]) for the treatment of hypertrophic cardiomyopathy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFICAMTEN (Myqorzo)** requires the following rule(s) be met for renewal:
- You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
- You have experienced continued clinical benefit (such as reduction of symptoms, New York Heart Association [NYHA] classification [a way to classify severity of symptoms] improvement)
- You will NOT use Myqorzo concurrently (at the same time) with another myosin inhibitor (such as Camzyos [mavacamten]) for the treatment of hypertrophic cardiomyopathy (a type of heart condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myqorzo.

REFERENCES

Myqorzo [Prescribing Information]. South San Francisco, CA: Cytokinetics Incorpo; December 2025.

Created: 06/26
Effective: 07/01/26 Client Approval: 06/26 DMC Approval: 06/16/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AFLIBERCEPT-AYYH

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AFLIBERCEPT-AYYH	PAVBLU	49830		GPI-10 (8665501014)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
- Pavblu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll], Eylea [aflibercept])

If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days for 3 fills.**

If no, continue to #2.

Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
- Pavblu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa], Eylea [aflibercept])
- The patient had a trial of or contraindication to ONE of the following preferred agents: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

If no, continue to #3.

Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
- Pavblu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa], Eylea [aflibercept])

If yes, **approve for 5 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

If no, continue to #4.

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AFLIBERCEPT-AYYH

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
Pavblu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab], Eylea [aflibercept])
The patient had a trial of or contraindication to ONE of the following preferred agents: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If yes, **approve for 5 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

If no, continue to #5.

Does the patient have a diagnosis of retinopathy of prematurity (ROP) (ICD-10 Group H35.1)?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.3mL per 30 days.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFLIBERCEPT-AYYH (Pavblu)** requires the following rule(s) be met for approval:
You have ONE of the following:
Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
Macular edema following retinal vein occlusion (RVO: a type of eye condition)
Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
Retinopathy of prematurity (ROP: a type of eye condition in babies that are born early)
(Initial denial text continued on next page)

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AFLIBERCEPT-AYYH

INITIAL CRITERIA (CONTINUED)

If you have neovascular (wet) age-related macular degeneration, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll], Eylea [aflibercept])

If you have macular edema following retinal vein occlusion, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa], Eylea [aflibercept])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If you have diabetic macular edema, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa], Eylea [aflibercept])

If you have diabetic retinopathy, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Eylea [aflibercept])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AFLIBERCEPT-AYYH

RENEWAL CRITERIA

NOTE: For the diagnosis of retinopathy of prematurity (ROP), please refer to the Initial Criteria section.

Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Pavblu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll], Eylea [aflibercept])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 56 days.**

If no, continue to #2.

Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Pavblu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa], Eylea [aflibercept])

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 56 days.**

If no, continue to #3.

Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Pavblu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa], Eylea [aflibercept])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 56 days.**

If no, continue to #4.

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AFLIBERCEPT-AYYH

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Pavblu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab], Eylea [aflibercept])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 56 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFLIBERCEPT-AYYH (Pavblu)** requires the following rule(s) be met for renewal:
You have ONE of the following:
Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
Macular edema following retinal vein occlusion (RVO: a type of eye condition)
Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
If you have neovascular (wet) age-related macular degeneration, renewal also requires:
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll], Eylea [aflibercept])
If you have macular edema following retinal vein occlusion, renewal also requires:
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa], Eylea [aflibercept])
(Renewal denial text continued on next page)

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AFLIBERCEPT-AYYH

RENEWAL CRITERIA (CONTINUED)

If you have diabetic macular edema, renewal also requires:
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa]), Eylea [aflibercept])

If you have diabetic retinopathy, renewal also requires:
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Pavblu concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Eylea [aflibercept])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Pavblu.

REFERENCES
Pavblu [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; August 2024.
Eylea [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2024.

Created: 10/24
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AFLIBERCEPT-EYLEA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AFLIBERCEPT	EYLEA		30919 34816	GPI-14 (8665501000E520, 86655010002020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
Eylea will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa])
The patient had a trial of or contraindication to ONE of the following preferred agents: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**
If no, continue to #2.

Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
Eylea will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab])
The patient had a trial of or contraindication to ONE of the following preferred agents: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If yes, **approve for 5 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**
If no, continue to #3.

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AFLIBERCEPT-EYLEA

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
Eylea will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If yes, **approve for 5 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**
If no, continue to #4.

Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
Eylea will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

If yes, **approve for 4 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days for 3 fills.**
If no continue to #5.

Does the patient have a diagnosis of retinopathy of prematurity (ROP) (ICD-10 Group H35.1)?

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.3mL per 30 days.**

If no, do not approve.
DENIAL TEXT: See the initial

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AFLIBERCEPT-EYLEA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFLIBERCEPT-EYLEA** requires the following rule(s) be met for approval:
You have ONE of the following:
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Retinopathy of prematurity (ROP: a type of eye condition in babies that are born early)

If you have macular edema following retinal vein occlusion, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If you have diabetic retinopathy, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

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AFLIBERCEPT-EYLEA

INITIAL CRITERIA (CONTINUED)

If you have diabetic macular edema, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If you have neovascular (wet) age-related macular degeneration, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AFLIBERCEPT-EYLEA

RENEWAL CRITERIA

NOTE: For the diagnosis of retinopathy of prematurity (ROP), please refer to the Initial Criteria section.

Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Eylea will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

If no, continue to #2.

Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Eylea will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab])

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 56 days.**

If no, continue to #3.

Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Eylea will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 56 days.**

If no, continue to #4.

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AFLIBERCEPT-EYLEA

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Eylea will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 56 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFLIBERCEPT-EYLEA** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)

If you have macular edema following retinal vein occlusion, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If you have diabetic retinopathy, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab])

If you have diabetic macular edema, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

(Renewal denial text continued on next page)

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AFLIBERCEPT-EYLEA

RENEWAL CRITERIA (CONTINUED)

If you have neovascular (wet) age-related macular degeneration, renewal also requires:

You have maintenance or improvement of visual acuity (vision clarity or sharpness)

You will NOT use Eylea concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eylea.

REFERENCES

Eylea [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2024.

Created: 04/14
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AFLIBERCEPT-EYLEA HD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AFLIBERCEPT	EYLEA HD		54599	GPI-14 (86655010002080)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
Eylea HD will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab])
The patient had a trial of or contraindication to ONE of the following preferred agents: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #0.14mL per 21 days for 3 fills.**

If no, continue to #2.

Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
Eylea HD will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If yes, **approve for 4 months by GPID or GPI-14 with a quantity limit of #0.14mL per 21 days for 3 fills.**

If no, continue to #3.

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AFLIBERCEPT-EYLEA HD

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
- Eylea HD will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

If yes, **approve for 4 months by GPID or GPI-14 with a quantity limit of #0.14mL per 21 days for 3 fills.**

If no, continue to #4.

Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
- Eylea HD will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa])
- The patient had a trial of or contraindication to ONE of the following preferred agents: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If yes, **approve for 5 months by GPID or GPI-14 with a quantity limit of #0.14mL per 21 days for 3 fills.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFLIBERCEPT-EYLEA HD** requires the following rule(s) be met for approval:
You have ONE of the following:
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)

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AFLIBERCEPT-EYLEA HD

INITIAL CRITERIA (CONTINUED)

If you have diabetic retinopathy, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

If you have diabetic macular edema, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If you have neovascular (wet) age-related macular degeneration, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

If you have macular edema following retinal vein occlusion, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AFLIBERCEPT-EYLEA HD

RENEWAL CRITERIA

Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Eylea HD will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab])

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.14mL per 21 days.**

If no, continue to #2.

Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Eylea HD will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.14mL per 21 days.**

If no, continue to #3.

Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
Eylea HD will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.14mL per 21 days.**

If no, continue to #4.

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AFLIBERCEPT-EYLEA HD

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD- 10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
- The patient has maintenance or improvement of visual acuity
- Eylea HD will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #0.14mL per 21 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AFLIBERCEPT-EYLEA HD** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
- Macular edema following retinal vein occlusion (RVO: a type of eye condition)

If you have diabetic retinopathy, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab])

If you have diabetic macular edema, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

If you have neovascular (wet) age-related macular degeneration, renewal also requires:
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

(Renewal denial text continued on next page)

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AFLIBERCEPT-EYLEA HD

RENEWAL CRITERIA (CONTINUED)

If you have macular edema following retinal vein occlusion, renewal also requires:
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You will NOT use Eylea HD concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Lucentis [ranibizumab], Vabysmo [faricimab-svoa])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Eylea HD.

REFERENCES
Eylea HD [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; November 2025.

Created: 08/23
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AGALSIDASE BETA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AGALSIDASE BETA	FABRAZYME	24861		GPI-10 (3090361010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
- Fabrazyme will NOT be used concurrently with another Fabry disease therapy (e.g., Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat])
- The patient is symptomatic OR has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the request for a female **AND** the patient meets the following criterion?
- The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

If yes, **approve for 6 months by HICL or GPI-10.**
If no, continue to #3.

Is the request for a male and the patient meets **ONE** of the following criteria?
- The patient has an alpha galactosidase A (a-Gal-A) deficiency as indicated by an enzyme assay
- The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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AGALSIDASE BETA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for approval:
You have Fabry disease (a rare genetic disease)
You are 2 years of age or older
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor), cardiologist (a type of heart doctor), or a doctor specializing in genetics or inherited metabolic disorders
You will NOT use Fabrazyme concurrently (at the same time) with another Fabry disease medication (such as Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat])
You are symptomatic OR have evidence of injury from GL-3 (globotriaosylceramide: a type of fat) to the kidney, heart, or central nervous system recognized by laboratory, histological (viewed by microscope), or imaging findings. Evidence of injury may include decreased glomerular filtration rate (GFR: a tool for evaluating kidney function) for age, persistent albuminuria (protein in urine), cerebral white matter lesions on brain MRI (magnetic resonance imaging: type of imaging lab), cardiac fibrosis (abnormal thickening of heart valves) on contrast cardiac MRI
If you are a female, approval also requires:
You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing
If you are a male, approval also requires ONE of the following:
You do NOT have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AGALSIDASE BETA

RENEWAL CRITERIA

Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) **AND** meet the following criterion?
Fabrazyme will NOT be used concurrently with another Fabry disease therapy (e.g., Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Has the patient demonstrated improvement, maintenance, or stabilization in **ONE** of the following while on therapy?
Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for renewal:
You have Fabry disease (a rare genetic disease)
You will NOT use Fabrazyme concurrently (at the same time) with another Fabry disease medication (such as Elfabrio [pegunigalsidase alfa-iwxj], Galafold [migalastat])
You have demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy:
Symptoms (such as pain, hypohidrosis [less sweating]/anhidrosis [no sweating], exercise intolerance, GI [gastrointestinal] symptoms, angiokeratomas [dark red-blue raised spots on the skin], abnormal cornea [a part of the eye], tinnitus [ringing in the ears]/hearing loss)
Imaging (such as brain/cardiac MRI [magnetic resonance imaging: type of imaging lab], DEXA [a type of bone scan], renal [kidney] ultrasound)
Laboratory or histological (viewed by microscope) testing (such as GL-3 [globotriaosylceramide: a type of fat] in plasma/urine, renal biopsy [removal of cells or tissue from the body for examination])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AGALSIDASE BETA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fabrazyme.

REFERENCES

Fabrazyme [Prescribing Information]. Cambridge, MA: Genzyme Corporation; July 2024.

Created: 02/19
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 07/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALECTINIB HCL	ALECENSA	42895		GPI-10 (2153050710)	

GUIDELINES FOR USE

Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer is anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient's cancer node positive or the tumor is at least 4 cm **AND** the patient meets the following criterion?
Alecensa will be used as adjuvant treatment following tumor resection

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
If no, continue to #3.

Is the patient's cancer metastatic?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALECTINIB (Alecensa)** requires the following rules be met for approval:
You have non-small cell lung cancer (NSCLC: a type of lung cancer)
You are 18 years of age or older
Your cancer is anaplastic lymphoma kinase (ALK)-positive (a type of abnormal gene change), as detected by a Food and Drug Administration (FDA)-approved test
You meet ONE of the following:
- Your cancer is node positive (cancer has spread to the lymph nodes) or your tumor is at least 4 cm, and Alecensa will be used as adjuvant (additional) treatment following tumor resection (surgical removal of a tumor)
- Your cancer is metastatic (has spread to other parts of the body)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALECTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alecensa.

REFERENCES

Alecensa [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; April 2024.

Created: 12/15
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALEMTUZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALEMTUZUMAB	LEMTRADA		36182	GPI-10 (6240501000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include relapsing-remitting disease or active secondary progressive disease, and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient had a trial of or contraindication to the preferred agent: Kesimpta (ofatumumab)

If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #6mL (five 1.2mL vials) for one fill.**

If no, do not approve.

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALEMTUZUMAB (Lemtrada)** requires the following rules be met for approval:
You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder) which includes relapsing-remitting disease (symptoms or disease returns and goes away) or active secondary progressive disease (advanced disease)
You are 18 years of age or older
You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALEMTUZUMAB

RENEWAL CRITERIA

Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include relapsing-remitting disease or active secondary progressive disease, **AND** meet the following criterion?
At least 12 months have elapsed since the patient received the most recent course of Lemtrada

If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #3.6mL (three 1.2mL vials) for one fill.**

If no, do not approve.
RENEWAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALEMTUZUMAB (Lemtrada)** requires the following rules be met for renewal:
You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes relapsing-remitting disease (symptoms or disease returns and goes away) or active secondary progressive disease (advanced disease)
At least 12 months have passed since you received the most recent course of Lemtrada

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Lemtrada.

REFERENCES

Lemtrada [Prescribing Information]. Cambridge, MA: Genzyme Corporation; May 2024.

Created: 02/15
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALGLUCOSIDASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALGLUCOSIDASE ALFA	LUMIZYME	33588		GPI-10 (3090771500)	

GUIDELINES FOR USE

Does the patient have a diagnosis of Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (ICD-10 E74.02)?

If yes, **approve for lifetime by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALGLUCOSIDASE ALFA (Lumizyme)** requires the following rule(s) be met for approval:
You have Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (a type of genetic disorder)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumizyme.

REFERENCES

Lumizyme [Prescribing Information]. Cambridge, MA: Genzyme Corporation; December 2024.

Created: 08/14
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-HOUSE DUST MITE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MITE,D.FARINAE-D.PTERONYSSINUS	ODACTRA		42527	GPI-14 (20109902220740)	ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of house dust mite (HDM)-induced allergic rhinitis (ICD-10 J30.89) and meet **ALL** of the following criteria?

- The patient is 5 to 65 years of age
- The patient's diagnosis is confirmed by in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, OR by skin testing to licensed house dust mite allergen extracts
- Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
- The patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
- The patient has moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
- The patient has a current claim or prescription for an auto-injectable epinephrine within the past 365 days

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-HOUSE DUST MITE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) be met for approval:
You have allergic rhinitis (itchy, watery eyes, sneezing) caused by house dust mites
You are 5 to 65 years of age
Your diagnosis is confirmed by in vitro testing (testing outside of the body in a tube) for IgE (immunoglobulin E) antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, OR by skin testing to licensed house dust mite allergen extracts
Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
You have moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, impairment of school or work)
You have a current claim or prescription for an auto-injectable epinephrine within the past 365 days

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-HOUSE DUST MITE

RENEWAL CRITERIA

Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) is met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline (before treatment)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Odactra.

REFERENCES

Odactra [Prescribing Information]. Hørsholm, Denmark: ALK-Abelló A/S; February 2025.

Created: 02/18
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-MIXED GRASS POLLEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GR POL-ORC/SW VER/RYE/KENT/TIM	ORALAIR	39918		GPI-10 (2010990520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of grass pollen-induced allergic rhinitis (ICD-10 J30.1) and meet **ALL** of the following criteria?

- The diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species (sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens) contained in Oralair
- Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
- The patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
- The patient has moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
- The patient has a current claim or prescription for auto-injectable epinephrine

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient 5 to 17 years of age?

If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
100 IR: Approve #3 for 1 fill.
300 IR: Approve #1 per day.

If no, continue to #3.

Is the patient between 18 and 65 years of age?

If yes, **approve the 300 IR strength for 12 months by GPID or GPI-10 with a quantity limit of #1 per day.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-MIXED GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for approval:

- You have allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
- Your diagnosis is confirmed by a positive skin test or in vitro testing (testing outside of the body in a tube) for pollen-specific IgE (immunoglobulin E) antibodies for any of the five grass types included in Oralair (sweet vernal, orchard, perennial rye, timothy, and Kentucky blue grass mixed pollens)
- Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
- You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
- You have moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
- You have a current claim or prescription for auto-injectable epinephrine
- You are 5 to 65 years of age

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-MIXED GRASS POLLEN

RENEWAL CRITERIA

Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by HICL or GPI-14 with a quantity limit of #1 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rules be met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline (before treatment)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oralair.

REFERENCES

Oralair [Prescribing Information]. Lenoir, NC: GREER Laboratories, Inc., December 2018.

Created: 05/14
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
WEED POLLEN-SHORT RAGWEED	RAGWITEK		36402	GPI-14 (20100060200720)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of short ragweed pollen-induced allergic rhinitis (ICD-10 J30.1) and meet **ALL** of the following criteria?

- The patient is 5 to 65 years of age
- Diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen
- Therapy was prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
- The patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
- The patient has moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
- The patient has a current claim or prescription for auto-injectable epinephrine

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for approval:
You have allergic rhinitis (itchy, watery eyes, sneezing) caused by short ragweed pollen
You are 5 to 65 years of age
Your diagnosis is confirmed by a positive skin test or in vitro testing (testing outside of the body in a tube) for pollen-specific IgE (immunoglobulin E) antibodies for short ragweed pollen
Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
You have moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
You have a current claim or prescription for auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

RENEWAL CRITERIA

Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis from baseline (before treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ragwitek.

REFERENCES

Ragwitek [Prescribing Information]. Swindon, UK: Catalent Pharma Solutions Limited; April 2022.

Created: 05/14
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GRASS POLLEN-TIMOTHY, STD	GRASTEK	22138		GPI-10 (2010004800)	ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of grass pollen-induced allergic rhinitis (ICD-10 J30.1) and meet **ALL** of the following criteria?

The patient is 5 to 65 years of age

The diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies for timothy grass or cross-reactive grass pollens

Therapy is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases

The patient has persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)

The patient has moderate to severe symptoms of allergic rhinitis (including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)

The patient has a current claim or prescription for auto-injectable epinephrine

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for approval:

You have allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen

You are 5 to 65 years of age

Your diagnosis is confirmed by a positive skin test or in vitro testing for pollen-specific IgE (immunoglobulin E) antibodies for timothy grass or cross-reactive grass pollens

Therapy is prescribed by or in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases

(Initial denial text continued on next page)

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

You have persistent symptoms of allergic rhinitis (defined as symptoms presenting for at least 4 days a week or for at least 4 weeks)
You have moderate to severe symptoms of allergic rhinitis including one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
You have a current claim or prescription for auto-injectable epinephrine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

RENEWAL CRITERIA

Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for renewal:
You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline (before treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Grastek.

REFERENCES

Grastek [Prescribing Information]. Hørsholm, Denmark: ALK-Abelló; September 2022.

Created: 05/14
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALPELISIB-PIQRAY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALPELISIB	PIQRAY	45761		GPI-10 (2153801000)	BRAND ≠ VIJOICE

GUIDELINES FOR USE

Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Groups C50, C79.81) and meet **ALL** of the following criteria?
Piqray will be used in combination with fulvestrant (Faslodex)
The patient's breast cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
The patient's tumor is PIK3CA-mutated, as detected by an FDA-approved test
The patient has disease progression on or after an endocrine-based regimen (e.g., letrozole, anastrozole, tamoxifen)

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
300mg daily dose: #56 per 28 days.
250mg daily dose: #56 per 28 days.
200mg daily dose: #28 per 28 days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALPELISIB-PIQRAY** requires the following rule(s) be met for approval:
You have advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
Piqray will be used in combination with fulvestrant (Faslodex)
Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
Your tumor has a PIK3CA mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
You have disease progression (condition has worsened) on or after an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALPELISIB-PIQRAY

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Piqray.

REFERENCES

Piqray [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.

Created: 08/19
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALPELISIB - VIJOICE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALPELISIB	VIJOICE	45761		GPI-10 (9948601000)	BRAND ≠ PIQRAY

GUIDELINES FOR USE

Does the patient have a diagnosis of PIK3CA-related overgrowth spectrum (PROS) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
The patient has severe manifestations of PROS that require systemic therapy

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
50 mg daily dose: #28 per 28 days.
125 mg daily dose: #28 per 28 days.
250 mg daily dose: #56 per 28 days.

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALPELISIB - VIJOICE** requires the following rule(s) be met for approval:
You have PIK3CA-related overgrowth spectrum (PROS: group of disorders that cause overgrowth of parts of the body due to mutations in a type of gene)
You are 2 years of age or older
You have severe manifestations of PROS that require systemic therapy (treatment that targets the entire body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vijoice.

REFERENCES
Vijoice [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corp.; April 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/22
Client Approval: 09/22
P&T Approval: 07/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ALPHA-1-PROTEINASE INHIBITOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ALPHA-1-PROTEINASE INHIBITOR	GLASSIA, PROLASTIN C, ARALAST NP, ZEMAIRA	04529		GPI-10 (4510001010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of clinically evident emphysema (ICD-10 Group J43) due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin [AAT] deficiency) (ICD-10 E88.01) and meet **ALL** of the following criteria?

The patient is 18 years of age or older

The requested medication will be used as chronic augmentation or maintenance therapy

Therapy is prescribed by or in consultation with a pulmonologist, allergist, or immunologist

The patient's alpha-1 antitrypsin deficiency genotype does NOT include a normal M gene (e.g., MZ)

The patient has an FEV1 of less than or equal to 65%

The patient is not currently smoking

The patient has a documented pre-treatment alpha1-antitrypsin (AAT) level of less than or equal to 57mg/dL or 11micromol/L

The patient does not have an IgA deficiency

The requested medication will NOT be used concurrently with another alpha-1-proteinase inhibitor (e.g., Glassia, Prolastin C, Aralast NP, Zemaira)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALPHA-1-PROTEINASE INHIBITOR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALPHA-1-PROTEINASE INHIBITOR (Glassia, Prolastin C, Aralast NP, Zemaira)** requires the following rule(s) be met for approval:

- You have clinically evident emphysema (a type of lung disease) due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin [AAT] deficiency) (a type of genetic condition)
- You are 18 years of age or older
- The requested medication will be used as chronic augmentation therapy (long-term replacement treatment) or maintenance therapy (taken on a regular basis)
- Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
- Your alpha-1 antitrypsin deficiency genotype (a set of genes) does NOT include a normal M gene (such as MZ [a type of gene])
- You have a forced expiratory volume (FEV1: amount of air exhaled in one second) of less than or equal to 65 percent
- You are not currently smoking
- You have a documented pre-treatment alpha1-antitrypsin (AAT: a type of protein) level of less than or equal to 57mg/dL or 11micromol/L
- You do not have an IgA deficiency (a type of condition where the immune system does not make enough of a type of antibody)
- You will NOT use the requested medication concurrently (at the same time) with another alpha-1-proteinase inhibitor (such as Glassia, Prolastin C, Aralast NP, Zemaira)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ALPHA-1-PROTEINASE INHIBITOR

RENEWAL CRITERIA

Does the patient have a diagnosis of clinically evident emphysema (ICD-10 Group J43) due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin [AAT] deficiency) (ICD-10 E88.01) and meet **ALL** of the following criteria?
The patient has shown clinical benefit (maintained or slowed progression of emphysema)
The patient is not currently smoking
The requested medication will NOT be used concurrently with another alpha-1-proteinase inhibitor (e.g., Glassia, Prolastin C, Aralast NP, Zemaira)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ALPHA-1-PROTEINASE INHIBITOR (Glassia, Prolastin C, Aralast NP, Zemaira)** requires the following rule(s) be met for renewal:
You have clinically evident emphysema (a type of lung disease) due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin [AAT] deficiency) (a type of genetic condition)
You have shown clinical benefit (improvement) (maintained or slowed progression of emphysema [a type of lung disease])
You are not currently smoking
You will NOT use the requested medication concurrently (at the same time) with another alpha-1-proteinase inhibitor (such as Glassia, Prolastin C, Aralast NP, Zemaira)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aralast NP, Glassia, Prolastin C, and Zemaira.

REFERENCES

Aralast NP [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; October 2024.
Glassia [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; February 2025.
Prolastin C [Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2022.
Zemaira [Prescribing Information]. Kankakee, IL: CSL Behring LLC; January 2024.

Created: 08/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMANTADINE EXTENDED RELEASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMANTADINE EXTENDED RELEASE	GOCOVRI		43787 43788	GPI-14 (73200010107020, (73200010107040)	
AMANTADINE HCL	OSMOLEX ER		44471 44472 44473 48017	GPI-14 (73200010107520, 73200010107530, 73200010107540, 7320001010C320)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

GOCOVRI

Does the patient have a diagnosis of Parkinson's disease (ICD-10 Group G20)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have dyskinesia and meet **ALL** of the following criteria?
The patient is receiving levodopa-based therapy
The patient had a trial of generic amantadine capsules, tablets, or solution

If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
68.5mg: #1 per day.
137mg: #2 per day.

If no, continue to #3.

Is the patient experiencing 'off' episodes and meets **ALL** of the following criteria?
Gocovri will be used as an adjunctive treatment to levodopa/carbidopa therapy
The patient had a trial of generic amantadine capsules, tablets, or solution

If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
68.5mg: #1 per day.
137mg: #2 per day.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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AMANTADINE EXTENDED RELEASE

GUIDELINES FOR USE - GOCOVRI (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMANTADINE EXTENDED RELEASE (Gocovri)** requires the following rule(s) be met for approval:
You have Parkinson's disease (type of movement disorder)
If you have dyskinesia (uncontrolled involuntary muscle movements), approval also requires:
You are receiving levodopa-based therapy
You have tried generic amantadine capsules, tablets, or solution
If you are experiencing 'off' episodes (period of symptoms in between doses), approval also requires:
Gocovri will be used as adjunctive (add-on) treatment to levodopa-carbidopa therapy
You have tried generic amantadine capsules, tablets, or solution

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMANTADINE EXTENDED RELEASE

GUIDELINES FOR USE (CONTINUED)

OSMOLEX ER

Does the patient have a diagnosis of Parkinson's disease (ICD-10 Group G20) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with a psychiatrist, neurologist, or geriatrician
The patient had a trial of generic amantadine IR capsules, tablets, or solution

If yes, **approve for 12 months by GPID or GPI-14 for all strengths with a quantity limit of #1 per day.**
If no, continue to #2.

Is the request for the treatment of drug-induced extrapyramidal symptoms (EPS) and the patient meets **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a psychiatrist, neurologist, or geriatrician
The patient had a trial of generic amantadine IR capsules, tablets, or solution

If yes, **approve for 12 months by GPID or GPI-14 for all strengths with a quantity limit of #1 per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMANTADINE EXTENDED RELEASE (Osmolex ER)** requires the following rule(s) be met for approval:
You have one of the following:
- Parkinson's disease (type of movement disorder)
- Drug-induced extrapyramidal symptoms (group of movement disorders)

If you have Parkinson's disease, approval also requires:
- Therapy is prescribed by or in consultation with a psychiatrist (mental disorder doctor), neurologist (nerve doctor), or geriatrician (doctor who specializes in treating older adults)
- You have tried generic amantadine immediate-release capsules, tablets or solution

If you have drug-induced extrapyramidal symptoms, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a psychiatrist (mental disorder doctor), neurologist (nerve doctor), or geriatrician (doctor who specializes in treating older adults)
- You have tried generic amantadine immediate-release capsules, tablets or solution

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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AMANTADINE EXTENDED RELEASE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gocovri and Osmolex ER.

REFERENCES

Gocovri [Prescribing Information]. Emeryville, CA: Adamas Pharma, LLC.; January 2021.
Osmolex ER [Prescribing Information]. Emeryville, CA: Adamas Pharma, LLC.; March 2021.

Created: 09/17
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMBRISENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMBRISENTAN	LETAIRIS, AMBRISENTAN	34849		GPI-10 (4016000700)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
The patient does NOT have idiopathic pulmonary fibrosis (IPF)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMBRISENTAN (Letairis)** requires the following rule(s) be met for approval:
You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
You do NOT have idiopathic pulmonary fibrosis (scarring of the lungs due to an unknown cause)
(Initial denial text continued on next page)

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AMBRISENTAN

INITIAL CRITERIA (CONTINUED)

Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
Mean pulmonary artery pressure (PAP) greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMBRISENTAN

RENEWAL CRITERIA

Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2)?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMBRISENTAN (Letairis)** requires the following rule(s) be met for renewal:
You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Letairis.

REFERENCES

Letairis [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 10/22
Client Approval: 06/24
P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIFAMPRIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIFAMPRIDINE	FIRDAPSE	36930		GPI-10 (7600001210)	
AMIFAMPRIDINE	RUZURGI	34158		GPI-10 (7600001200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) (ICD-10 G70.80) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a neurologist or hematologist-oncologist
- The patient's diagnosis is confirmed by ALL of the following:
  - Electrodiagnostic studies (e.g., reduced compound muscle action potential (CMAP)) and/or voltage-gated calcium channel (VGCC) antibody testing
  - Clinical triad of muscle weakness, autonomic dysfunction, and decreased tendon reflexes

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the request for **Firdapse** and the patient meets the following criterion?
- The patient is 6 years of age or older

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10 per day.**
If no, continue to #3.

Is the request for **Ruzurgi**?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10 per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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AMIFAMPRIDINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for approval:
You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
Therapy is prescribed by or in consultation with a neurologist (type of brain doctor) or hematologist-oncologist (a type of blood-cancer doctor)
Your diagnosis is confirmed by ALL of the following:
- Electrodiagnostic studies and/or voltage-gated calcium channel (types of lab tests) antibody testing
- Three clinical symptoms of muscle weakness, autonomic dysfunction (nerve dysfunction), and decreased tendon reflexes

If you are requesting Firdapse, approval also requires:
- You are 6 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIFAMPRIDINE

RENEWAL CRITERIA

Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) (ICD-10 G70.80) **AND** meet the following criterion?
The patient has experienced improvement or stabilization in muscle weakness compared to baseline

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #10 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for renewal:
You have Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
You have experienced improvement or stabilization in muscle weakness compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Firdapse and Ruzurgi.

REFERENCES

Firdapse [Prescribing Information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc; May 2024.
Ruzurgi [Prescribing Information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 02/19
Client Approval: 06/24
P&T Approval: 10/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIKACIN LIPOSOMAL INHALATION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIKACIN LIPOSOMAL/NEB. ACCESSR	ARIKAYCE	45298		GPI-10 (0700001012)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of *Mycobacterium avium complex* (MAC) lung disease (ICD-10 A31.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has limited or no alternative treatment options
- The patient has NOT achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy
- Arikayce will be used as part of a combination antibacterial drug regimen

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8.4mL per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for approval:
- You have *Mycobacterium avium complex* (MAC: a type of bacteria) lung disease
- You are 18 years of age or older
- You have limited or no alternative treatment options
- You have NOT achieved negative sputum cultures (mucus tests) after using multidrug background regimen therapy for at least 6 months in a row
- Arikayce will be used as part of a combination antibacterial drug regimen

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIKACIN LIPOSOMAL INHALATION

RENEWAL CRITERIA

Does the patient have a diagnosis of *Mycobacterium avium complex* (MAC) lung disease (ICD-10 A31.0) and meet **ALL** of the following criteria?
The patient has NOT had a positive MAC sputum culture after consecutive negative cultures
The patient has had an improvement in symptoms

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8.4mL per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for renewal:
You have *Mycobacterium avium complex* (MAC: a type of bacteria) lung disease
You have NOT had a positive *Mycobacterium avium complex* sputum culture (mucus test) after repeated negative cultures
You have experienced an improvement in symptoms

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arikayce.

REFERENCES

Arikayce [Prescribing information]. Bridgewater, NJ: Insmed Incorporated; December 2025.

Created: 11/18
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 10/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMIVANTAMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMIVANTAMAB-VMJW	RYBREVANT	47385		GPI-10 (2135971080)	
AMIVANTAMAB-HYALURONIDASE-LPUJ	RYBREVANT FASPRO	51068		GPI-10 (2199000203)	

GUIDELINES FOR USE

Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations?

If yes, continue to #3.
If no, continue to #5.

Does the patient meet **ALL** of the following criteria?
The patient's mutation is detected by an FDA-approved test
The requested medication will be used in combination with lazertinib (Lazcluze)

If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
Rybrevant
Rybrevant Faspro

If no, continue to #4.

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AMIVANTAMAB

GUIDELINES FOR USE (CONTINUED)

Does the patient meet **ALL** of the following criteria?
- The requested medication will be used in combination with carboplatin and pemetrexed
- The patient's disease has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tagrisso [osimertinib], Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
Rybrevant
Rybrevant Faspro

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, and meet **ONE** of the following criteria?
- The requested medication will be used in combination with carboplatin and pemetrexed
- The requested medication will be used as a single agent and the patient's disease has progressed on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin)

If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
Rybrevant
Rybrevant Faspro

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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AMIVANTAMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMIVANTAMAB (Rybrevant, Rybrevant Faspro)** requires the following rule(s) be met for approval:

You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue, lymph nodes, or other parts of the body)

You are 18 years of age or older

If you have epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R substitution mutations (abnormal changes in a type of gene), approval also requires ONE of the following:

Your mutation is detected by a Food and Drug Administration (FDA)-approved test AND the requested medication will be used in combination with lazertinib (Lazcluze)

The requested medication will be used in combination with carboplatin and pemetrexed AND your disease has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (such as Tagrisso [osimertinib], Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If you have epidermal growth factor receptor (EGFR: type of protein) exon 20 insertion mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, approval also requires you meet ONE of the following:

The requested medication will be used in combination with carboplatin and pemetrexed

The requested medication will be used as a single agent AND your disease has progressed on or after platinum-based chemotherapy (such as cisplatin, carboplatin)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rybrevant and Rybrevant Faspro.

REFERENCES

Rybrevant [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; November 2025.
Rybrevant Faspro [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; December 2025.

Created: 07/21
Effective: 01/12/26 Client Approval: 01/26 P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AMLODIPINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMLODIPINE BESYLATE	NORLIQVA	06494		GPI-10 (3400000310)	BRAND = NORLIQVA

GUIDELINES FOR USE

Does the patient have a diagnosis of hypertension (ICD-10 I10) **AND** meet the following criterion?
The patient has a contraindication to or is unable to swallow amlodipine tablets

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
If no, continue to #2.

Does the patient have a diagnosis of chronic stable angina (ICD-10 I20.9, I20.89) **AND** meet the following criterion?
The patient has a contraindication to or is unable to swallow amlodipine tablets

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
If no, continue to #3.

Does the patient have a diagnosis of confirmed or suspected vasospastic angina (Prinzmetal's or variant angina) (ICD-10 I20.1) **AND** meet the following criterion?
The patient has a contraindication to or is unable to swallow amlodipine tablets

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
If no, continue to #4.

Does the patient have a diagnosis of angiographically documented coronary artery disease (CAD) (ICD-10 Group I25) and meet **ALL** of the following criteria?
The patient does not have heart failure OR an ejection fraction of less than 40%
The patient has a contraindication to or is unable to swallow amlodipine tablets

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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AMLODIPINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMLODIPINE (Norliqva)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Hypertension (high blood pressure)
- Chronic stable angina (a type of heart condition)
- Confirmed or suspected vasospastic angina (Prinzmetal's or variant angina) (a type of heart condition)
- Angiographically documented coronary artery disease (a type of heart condition that has been confirmed by a type of imaging test)

If you have hypertension, approval also requires:
- You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

If you have chronic stable angina, approval also requires:
- You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

If you have confirmed or suspected vasospastic angina (Prinzmetal's or variant angina), approval also requires:
- You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

If you have angiographically documented coronary artery disease (CAD), approval also requires:
- You do not have heart failure (a type of heart condition) OR an ejection fraction (evaluates heart function) of less than 40 percent
- You have a contraindication to (harmful for you to use) or are unable to swallow amlodipine tablets

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Norliqva.

REFERENCES
Norliqva [Prescribing Information]. Farmville, NC: CMP Pharma, Inc.; February 2022.

Created: 07/25
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANABOLIC STEROIDS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OXYMETHOLONE	ANADROL-50	01409		GPI-10 (2320005000)	
OXANDROLONE	OXANDRIN, OXANDROLONE	01412		GPI-10 (2320004000)	FDB: ROUTE ≠ MISCELL.

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ANADROL-50

Does the patient have a diagnosis of anemia caused by acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, hypoplastic anemias, or Fanconi's anemia (ICD-10 Group D61) **AND** meet the following criterion?
The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, continue to #2.
If no, continue to #3.

Does the patient have **ANY** of the following contraindications to anabolic steroid therapy?
Known or suspected carcinoma of the prostate or breast in male patients
Known or suspected carcinoma of the breast in females with hypercalcemia
Known or suspected nephrosis (the nephrotic phase of nephritis)
Known or suspected hypercalcemia
Severe hepatic dysfunction

If yes, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, **approve for 6 months by HICL or GPI-10.**

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INITIAL CRITERIA - ANADROL-50 (CONTINUED)

Does the patient have a diagnosis of cachexia associated with AIDS (ICD-10 R64) and meet **ALL** of the following criteria?
- The patient is on anti-retroviral therapy
- The patient has a viral load of less than 200 copies per mL within the past 3 months
- Therapy is prescribed by or in consultation with a gastroenterologist, nutritional support specialist (SBS) or infectious disease specialist
- The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient has 10% unintentional weight loss over 12 months
- The patient has 7.5% unintentional weight loss over 6 months
- The patient has 5% body cell mass (BCM) loss within 6 months
- The patient has a body cell mass (BCM) of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
- The patient has a body cell mass (BCM) of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
- The patient has a BMI of less than 18.5 kg per meter squared

If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have **ANY** of the following contraindications to anabolic steroid therapy?
- Known or suspected carcinoma of the prostate or breast in male patients
- Known or suspected carcinoma of the breast in females with hypercalcemia
- Known or suspected nephrosis (the nephrotic phase of nephritis)
- Known or suspected hypercalcemia
- Severe hepatic dysfunction

If yes, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, **approve for 12 weeks by HICL or GPI-10.**

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ANABOLIC STEROIDS

INITIAL CRITERIA - ANADROL-50 (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANABOLIC STEROIDS (Anadrol-50)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Anemia (lack of healthy red blood cells) caused by acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, hypoplastic anemias, or Fanconi's anemia
- Cachexia (severe weight and muscle loss) associated with AIDS (acquired immune deficiency syndrome: a type of immune system disorder caused by a virus infection)

You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes

You do not have ANY of the following contraindications to (harmful for you to use) anabolic steroid therapy:
- Known or suspected prostate or breast cancer in male patients
- Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
- Known or suspected nephrosis (type of kidney disorder)
- Known or suspected hypercalcemia (high calcium levels)
- Severe hepatic (liver) dysfunction

If you have cachexia associated with AIDS, approval also requires:
- You are on anti-retroviral therapy (therapy that treats a type of viral infection)
- You have a viral load (amount of virus in your blood) of less than 200 copies per mL within the past 3 months
- Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist (SBS), or infectious disease specialist
- You meet ONE of the following:
  - You have 10% unintentional weight loss over 12 months
  - You have 7.5% unintentional weight loss over 6 months
  - You have 5% body cell mass (BCM) loss within 6 months
  - You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
  - You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
  - You have a BMI of less than 18.5 kg per meter squared

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANABOLIC STEROIDS

INITIAL CRITERIA (CONTINUED)

OXANDRIN

Is the request for adjunctive therapy to promote weight gain and the patient meets **ALL** of the following criteria?
The patient's weight loss is caused by extensive surgery, chronic infections, or severe trauma
The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, continue to #2.
If no, continue to #3.

Does the patient have **ANY** of the following contraindications to anabolic steroid therapy?
Known or suspected carcinoma of the prostate or breast in male patients
Known or suspected carcinoma of the breast in females with hypercalcemia
Known or suspected nephrosis (the nephrotic phase of nephritis)
Known or suspected hypercalcemia
Severe hepatic dysfunction

If yes, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, **approve for 12 weeks by HICL or GPI-10.**

Is the request for adjunctive therapy to offset the protein catabolism associated with prolonged administration of corticosteroids?

If yes, continue to #6.
If no, continue to #4.

Is the request for the relief of thebone pain accompanying osteoporosis (ICD-10 Groups M80, M81)?

If yes, continue to #6.
If no, continue to #5.

Does the patient have a diagnosis of Turner's syndrome (ICD-10 Group Q96)?

If yes, continue to #6.
If no, continue to #8.

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

Will the patient be monitored for peliosis hepatis, liver cell tumors and blood lipid changes?

If yes, continue to #7.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have **ANY** of the following contraindications to anabolic steroid therapy?
Known or suspected carcinoma of the prostate or breast in male patients
Known or suspected carcinoma of the breast in females with hypercalcemia
Known or suspected nephrosis (the nephrotic phase of nephritis)
Known or suspected hypercalcemia
Severe hepatic dysfunction

If yes, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, **approve for 6 months by HICL or GPI-10.**

Does the patient have a diagnosis of cachexia associated with AIDS (ICD-10 R64) and meet **ALL** of the following criteria?
The patient is on anti-retroviral therapy
The patient has a viral load of less than 200 copies per mL within the past 3 months
Therapy is prescribed by or in consultation with a gastroenterologist, nutritional support specialist (SBS) or infectious disease specialist
The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, continue to #9.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has 10% unintentional weight loss over 12 months,
- The patient has 7.5% unintentional weight loss over 6 months
- The patient has 5% body cell mass (BCM) loss within 6 months
- The patient has a body cell mass (BCM) of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
- The patient has a body cell mass (BCM) of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
- The patient has a BMI of less than 18.5 kg per meter squared

If yes, continue to #10.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have **ANY** of the following contraindications to anabolic steroid therapy?
- Known or suspected carcinoma of the prostate or breast in male patients
- Known or suspected carcinoma of the breast in females with hypercalcemia
- Known or suspected nephrosis (the nephrotic phase of nephritis)
- Known or suspected hypercalcemia
- Severe hepatic dysfunction

If yes, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, **approve for 12 weeks by HICL or GPI-10.**

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANABOLIC STEROIDS (Oxandrin, oxandrolone)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Weight loss
- Protein catabolism (breakdown) caused by long-term use of corticosteroids
- Bone pain accompanying osteoporosis (type of bone condition)
- Turner's syndrome (type of genetic disorder)
- Cachexia (severe weight and muscle loss) associated with AIDS (acquired immune deficiency syndrome: a type of immune system disorder caused by a virus infection)

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ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes
You do not have ANY of the following contraindications to (harmful for you to use) anabolic steroid therapy:
- Known or suspected prostate or breast cancer in male patients
- Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
- Known or suspected nephrosis (type of kidney disorder)
- Known or suspected hypercalcemia (high calcium levels)
- Severe hepatic (liver) dysfunction

If you have weight loss, approval also requires:
- Your weight loss is caused by extensive surgery, chronic infections, or severe trauma
- The medication is being used as add-on therapy to help weight gain

If you have cachexia associated with AIDS, approval also requires:
- You are on anti-retroviral therapy (treatment for a type of viral infection)
- You have a viral load (amount of virus in the blood) of less than 200 copies per mL within the past 3 months
- Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist (SBS) or infectious disease specialist
- You meet ONE of the following:
  - You have 10% unintentional weight loss over 12 months
  - You have 7.5% unintentional weight loss over 6 months
  - You have 5% body cell mass (BCM) loss within 6 months
  - You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
  - You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
  - You have a BMI of less than 18.5 kg per meter squared

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANABOLIC STEROIDS

RENEWAL CRITERIA

NOTE: For the diagnoses of anemia, weight loss, protein catabolism associated with prolonged administration of corticosteroids, bone pain accompanying osteoporosis, or Turner's syndrome, please refer to the Initial Criteria section.

OXANDRIN and ANADROL-50

Does the patient have a diagnosis of cachexia associated with AIDS (ICD-10 R64) and the patient meet **ALL** of the following criteria?
- The patient is on anti-retroviral therapy
- The patient's viral load is less than 200 copies per mL within the past 3 months
- The patient has responded to therapy as measured by at least a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks)
- The patient has not received more than 24 weeks of therapy in a calendar year

If yes, **approve for 12 weeks by HICL or GPI-10.** (**Note**: therapy is limited to 24 weeks per calendar year.)

If no, do not approve.

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ANABOLIC STEROIDS (Oxandrin, oxandrolone, Anadrol-50)** requires the following rule(s) be met for renewal:
- You have cachexia (severe weight and muscle loss) associated with AIDS (acquired immune deficiency syndrome: a type of immune system disorder caused by a virus infection)
- You are on anti-retroviral therapy (treatment for a type of viral infection)
- Your viral load (amount of virus in the blood) is less than 200 copies per mL within the past 3 months
- You have had a 10% increase in weight from baseline (before treatment) (current weight must have been measured within the last 4 weeks)
- You have not received more than 24 weeks of therapy in a calendar year

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ANABOLIC STEROIDS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Anadrol-50 and Oxandrin.

REFERENCES

Anadrol-50 [Prescribing Information]. Marietta, GA: Alaven Pharmaceutical LLC; October 2012
Oxandrin [Prescribing Information]. East Brunswick, NJ: Savient Pharmaceuticals; April 2007.

Created: 05/15
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 05/15

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANAKINRA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANAKINRA	KINERET	22953		GPI-10 (6626001000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

If yes, **do not approve**. [NOTE: This indication is for hospital use only.]
DENIAL TEXT: See initial denial text at the end of the guideline.

If no, continue to #2.

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist
Kineret will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

If yes, continue to #3.
If no, continue to #4.

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
- The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.67 mL per day.**
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of cryopyrin-associated periodic syndromes (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID) (ICD-10 M04.2) and meet **ALL** of the following criteria?
- The patient has genetic testing for gain-of-function mutations in the *NLRP3* gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein [SAA] or S100 proteins)
- The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
- Kineret will NOT be used concurrently with another systemic biologic (e.g., Arcalyst [rilonacept]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CAPS, including NOMID

  If yes, **approve for lifetime by HICL or GPI-10.**
  If no, continue to #5.

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA) (ICD-10 M04.8) and meet **ALL** of the following criteria?
- The patient has genetic testing for gain-of-function mutations in the *IL1RN* gene OR has inflammatory markers (i.e., elevated CRP, ESR)
- The patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis)
- Kineret will NOT be used concurrently with another systemic biologic (e.g., Arcalyst [rilonacept]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DIRA

If yes, **approve for lifetime by HICL or GPI-10.**
If no, continue to #6.

Does the patient have a diagnosis of Active Still's Disease/Adult-Onset Still's Disease (AOSD) (ICD- 10 M06.1) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
- Kineret will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of Active Still's Disease/AOSD

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1.34 mL per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Cryopyrin-associated periodic syndromes (CAPS: a type of immune disorder) including neonatal-onset multisystem inflammatory disease (NOMID: a type of immune system disorder)
- Deficiency of interleukin-1 receptor antagonist (DIRA: a type of immune system disorder)
- Active Still's Disease/Adult-Onset Still's Disease (AOSD) (an autoinflammatory disease)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Enbrel (etanercept)
    - Adalimumab-ryvk/adalimumab-aaty
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - You have tried a TNF inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

If you have cryopyrin-associated periodic syndromes, including neonatal-onset multisystem inflammatory disease, approval also requires:
- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
- You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), skeletal (bone) abnormalities
- You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Cryopyrin-Associated Periodic Syndromes, including Neonatal-Onset Multisystem Inflammatory Disease (types of immune system disorder)

If you have deficiency of interleukin-1 receptor antagonist, approval also requires:
- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN gene* (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body])
- You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: nail shedding)
- You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (a type of immune system disorder)

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

If you have Active Still's Disease/Adult-Onset Still's Disease, approval also requires:

Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)

You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Active Still's Disease/Adult-Onset Still's Disease (an autoinflammatory disease)

E. NOTE: Kineret will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ANAKINRA

RENEWAL CRITERIA

NOTE: For the diagnoses of cryopyrin-associated periodic syndromes (CAPS), including neonatal-onset multisystem inflammatory disease (NOMID), and deficiency of interleukin-1 receptor antagonist (DIRA), please refer to the Initial Criteria section.

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Kineret will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, continue to #2.
If no, continue to #3.

Does the patient meet **ONE** of the following criteria?
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
- The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.67 mL per day.**
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ANAKINRA

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of Active Still's Disease/Adult-Onset Still's Disease (AOSD) (ICD- 10 M06.1) and meet **ALL** of following criteria?

Kineret will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of Active Still's Disease/AOSD

The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis) or the patient has achieved a reduction in corticosteroid (e.g., prednisone) dose

The patient's disease is still clinically active (remission has not been attained) OR discontinuing therapy will result in harm to the patient

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.34 mL per day.** If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANAKINRA (Kineret)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Active Still's Disease/Adult-Onset Still's Disease (AOSD) (an autoinflammatory disease)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
You meet ONE of the following:
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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ANAKINRA

RENEWAL CRITERIA (CONTINUED)

You have tried a TNF inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have Active Still's Disease/Adult-Onset Still's Disease, renewal also requires:

- You will NOT use Kineret concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Active Still's Disease/Adult-Onset Still's Disease (an autoinflammatory disease)
- You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis [a type of joint condition]) or you have achieved a reduction (decrease) in corticosteroid (such as prednisone) dose
- Your disease is still clinically active (remission [reduction or disappearance of the signs and symptoms of a disease] has not been attained) OR discontinuing therapy will be harmful for you

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kineret.

REFERENCES

Kineret [Prescribing Information]. Stockholm, Sweden: Swedish Orphan Biovitrum; October 2025.

Created: 02/03
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANIFROLUMAB-FNIA (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANIFROLUMAB-FNIA	SAPHNELO	47512		GPI-10 (9942701025)	ROUTE = INTRAVEN

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient is receiving standard SLE therapy (e.g., oral corticosteroids, antimalarials, or immunosuppressants)
- Saphnelo will NOT be used concurrently with another systemic biologic (e.g., Benlysta [belimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANIFROLUMAB-FNIA (Saphnelo)** requires the following rule(s) be met for approval:
- You have moderate to severe systemic lupus erythematosus (SLE: a type of immune condition)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are receiving standard SLE therapy (such as oral corticosteroids, antimalarials, or immunosuppressants)
- You will NOT use Saphnelo concurrently (at the same time) with another systemic biologic (such as Benlysta [belimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANIFROLUMAB-FNIA (NSA)

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
The patient has shown clinical improvement while on Saphnelo
Saphnelo will NOT be used concurrently with another systemic biologic (e.g., Benlysta [belimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ANIFROLUMAB-FNIA (Saphnelo)** requires the following rule(s) be met for renewal:
You have moderate to severe systemic lupus erythematosus (SLE: a type of immune condition)
You have shown clinical improvement while on Saphnelo
You will NOT use Saphnelo concurrently (at the same time) with another systemic biologic (such as Benlysta [belimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Saphnelo.

REFERENCES

Saphnelo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, August 2024.

Created: 08/21
Effective: 07/31/26 Client Approval: 07/26 P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANIFROLUMAB-FNIA SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANIFROLUMAB-FNIA	SAPHNELO	47512		GPI-10 (9942701025)	ROUTE = SUBCUTANE.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient is currently using ONE clinical standard of care agent: corticosteroid (e.g., prednisone), antimalarial (e.g., hydroxychloroquine), NSAID (e.g., ibuprofen), immunosuppressive agent (e.g., azathioprine, cyclosporine)
- Saphnelo will NOT be used concurrently with another systemic biologic (e.g., Benlysta [belimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: Our guideline named **ANIFROLUMAB-FNIA SQ (Saphnelo)** requires the following rule(s) be met for approval:
- You have moderate to severe systemic lupus erythematosus (SLE: a type of immune condition)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are currently using ONE clinical standard of care medication: oral corticosteroid (such as prednisone), antimalarial (such as hydroxychloroquine), non-steroidal anti-inflammatory drug (NSAID, such as ibuprofen), immunosuppressive agent (such as azathioprine, cyclosporine)
- You will NOT use Saphnelo concurrently (at the same time) with another systemic biologic (such as Benlysta [belimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus (a type of immune condition)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANIFROLUMAB-FNIA SQ

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
- The patient has shown clinical improvement while on Saphnelo
- Saphnelo will NOT be used concurrently with another systemic biologic (e.g., Benlysta [belimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: Our guideline named **ANIFROLUMAB-FNIA SQ (Saphnelo)** requires the following rule(s) be met for renewal:
- You have moderate to severe systemic lupus erythematosus (SLE: a type of immune condition)
- You have shown clinical improvement while on Saphnelo
- You will NOT use Saphnelo concurrently (at the same time) with another systemic biologic (such as Benlysta [belimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus (a type of immune condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Saphnelo.

REFERENCES

Saphnelo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, April 2026.

Created: 08/21
Effective: 08/01/26 DMC Approval: 07/21/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APALUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APALUTAMIDE	ERLEADA	44773		GPI-10 (2140241000)	

GUIDELINES FOR USE

Does the patient have **ONE** of the following diagnoses?
Metastatic castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61)
Non-metastatic castration-resistant prostate cancer (nmCRPC) (ICD-10 Z19.2, C61)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
The patient has received a bilateral orchiectomy
The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
Erleada will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
60 mg: #4 per day.
240 mg: #1 per day.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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APALUTAMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
- Non-metastatic castration-resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)

You meet ONE of the following:
- You have received a bilateral orchiectomy (both testicles have been surgically removed)
- You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
- Erleada will be used together with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the prescribing information and/or drug monograph for Erleada.

REFERENCES
Erleada [Prescribing Information]. Horsham, PA: Janssen Products, LP; August 2024.

Created: 05/18
Effective: 03/04/26 Client Approval: 03/26 P&T Approval: 04/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE - APOKYN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE HCL	APOKYN, APOMORPHINE HCL		42078	GPI-14 (7320301010E220)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a neurologist
- The requested medication will be used for the acute, intermittent treatment of hypomobility, 'OFF' episodes associated with advanced Parkinson's disease
- The patient is experiencing at least 3 hours of “off” time on current Parkinson’s disease drug treatment
- The patient has demonstrated a clear responsiveness to treatment with levodopa

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient is unable to swallow extended-release tablets or administer extended-release capsules via a feeding tube
- The patient has failed to adhere to an oral carbidopa/levodopa regimen or tolerate carbidopa/levodopa regimen via a feeding tube

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Has the physician optimized the patient's medication therapy as evidenced by **ALL** of the following?
- The patient had a change in levodopa/carbidopa dosing strategy or formulation
- The patient had a trial of or contraindication to TWO Parkinson disease agents from two different classes: dopamine agonist (ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (entacapone, tolcapone), adenosine receptor antagonist A2A (Nourianz [istradefylline])

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #60mL per 30 days.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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APOMORPHINE - APOKYN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - APOKYN** requires the following rule(s) be met for approval:
You have advanced Parkinson's disease (PD: a type of movement disorder)
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
The requested medication will be used for acute, intermittent treatment of hypomobility, 'OFF' episodes (period of symptoms in between doses) associated with advanced Parkinson's disease (a type of movement disorder)
You are experiencing at least 3 hours of 'off' time (period of symptoms in between doses) on your current Parkinson's disease drug treatment (medication for a type of movement disorder)
You have shown a clear responsiveness to treatment with levodopa
You meet ONE of the following:
- You are unable to swallow extended-release tablets or administer extended-release capsules through a feeding tube
- You have failed to adhere to (keep up with) an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen through a feeding tube

Your doctor has optimized your medication therapy as shown by ALL of the following:
- You had a change in levodopa/carbidopa dosing strategy or formulation
- You have tried or have a contraindication to (harmful for you to use) TWO Parkinson disease medications from two different classes: dopamine agonist (ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (entacapone, tolcapone), adenosine receptor antagonist A2A (Nourianz [istradefylline])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APOMORPHINE - APOKYN

RENEWAL CRITERIA

Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) **AND** meet the following criterion?

The patient has experienced improvement with motor fluctuations during 'OFF' episodes while on the requested medication (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #60mL per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - APOKYN** requires the following rule(s) be met for renewal:

You have advanced Parkinson's disease (PD: a type of movement disorder)

You have experienced improvement with motor fluctuations (changes in the ability to move) during 'OFF' episodes with the use of the requested medication (such as improvement in speech, facial expression, tremor [shaking] at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Apokyn.

REFERENCES

Apokyn [Prescribing Information]. Rockville, MD: MDD US Operations, LLC, January 2025.

Created: 11/04
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE - ONAPGO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE HCL	ONAPGO	01934		GPI-10 (7320301010)	BRAND = ONAPGO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?

Onapgo will be used for the treatment of motor fluctuations associated with Parkinson's disease

Therapy is prescribed by or in consultation with a neurologist

The patient's disease is responsive to treatment with levodopa

The patient's current medication regimen, including levodopa, has been at a stable dose for at least 28 days

The patient has motor symptoms that are currently uncontrolled (defined as an average 'off' time of at least 3 hours per day, with a minimum of 2 hours each day)

The patient does not have any of the following: orthostatic hypotension, history of prolonged QTc (greater than 450 msec for male or greater than 470 msec for female), active or uncontrolled psychosis, active or uncontrolled depression

If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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APOMORPHINE - ONAPGO

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - ONAPGO** requires the following rule(s) be met for approval:
You have advanced Parkinson's disease (PD: a type of movement disorder)
Onapgo will be used for the treatment of motor fluctuations (changes in the ability to move) associated with Parkinson's disease
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
Your disease is responsive to treatment with levodopa
Your current medication regimen (treatment plan), including levodopa, has been at a stable dose for at least 28 days
Your motor symptoms are currently uncontrolled (defined as an average 'off' time of at least 3 hours per day, with a minimum of 2 hours each day)
You do not have any of the following: orthostatic hypotension (a type of low blood pressure), history of prolonged QTc (a type of irregular heart rhythm) (greater than 450 msec for male or greater than 470 msec for female), active or uncontrolled psychosis (a type of mental health disorder), active or uncontrolled depression (a type of mental health disorder)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APOMORPHINE - ONAPGO

RENEWAL CRITERIA

Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) **AND** meet the following criterion?
The patient has experienced improvement in motor symptoms while on Onapgo

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE - ONAPGO** requires the following rule(s) be met for renewal:
You have advanced Parkinson's disease (PD: a type of movement disorder)
You have experienced improvement in motor symptoms while on Onapgo

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Onapgo.

REFERENCES

Onapgo [Prescribing Information]. Rockville, MD: Supernus Pharmaceuticals, Inc.; February 2025.

Created: 02/25
Effective: 03/10/25 Client Approval: 03/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APREMILAST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APREMILAST	OTEZLA, OTEZLA XR	40967		GPI-10 (6670001500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
The patient is 6 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PsA

If yes, **enter approval(s) by GPID or GPI-14 as follows:**
If the starter pack is requested for dosage titration, approve for #1 fill for the requested starter pack as follows:
10-20-30-75mg: #41 tablets per 28 days.
10-20-30mg Two Week Starter Pack: #27 tablets per 14 days.
10-20-30mg 28-day Starter Pack: #55 tablets per 28 days.
10-20mg 28-day Starter Pack: #55 tablets per 28 days.
Approve the requested strength for 6 months as follows:
75mg XR: #1 per day.
30mg: #2 per day.
20mg: #2 per day.

If no, continue to #2.

Does the patient have a diagnosis of plaque psoriasis (PsO) (ICD-10 L40.0)?

If yes, continue to #3.
If no, continue to #8.

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APREMILAST

INITIAL CRITERIA (CONTINUED)

Is the patient's disease mild and the patient meets **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient had a trial of or contraindication to ONE clinical standard of care agent: a conventional systemic agent (e.g., methotrexate, acitretin, cyclosporine) OR a conventional topical agent (e.g., topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate])
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of mild PsO

If yes, continue to #4.
If no, continue to #5.

Does the patient meet **ONE** of the following criteria?
- The patient was previously stable on another biologic and is switching to the requested medication
- The patient has a static Physician Global Assessment (sPGA) score of 2
- The patient has a Psoriasis Area and Severity Index (PASI) score of 2 to 9

If yes, **enter approval(s) by GPID or GPI-14 as follows:**
If the starter pack is requested for dosage titration, approve for #1 fill for the requested starter pack as follows:
10-20-30-75mg: #41 tablets per 28 days.
10-20-30mg Two Week Starter Pack: #27 tablets per 14 days.
10-20-30mg 28-day Starter Pack: #55 tablets per 28 days.
Approve the requested strength for 6 months as follows:
75mg XR: #1 per day.
30mg: #2 per day.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's disease moderate to severe and the patient meets **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of moderate to severe PsO

If yes, continue to #6.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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APREMILAST

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to BOTH clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor, or JAK inhibitor for the same indication

If yes, continue to #7.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient was previously stable on another biologic and is switching to the requested medication
- The patient has psoriasis covering 3 percent or more of body surface area (BSA)
- The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

If yes, **enter approval(s) by GPID or GPI-14 as follows:**
If the starter pack is requested for dosage titration, approve for #1 fill for the requested starter pack as follows:
10-20-30-75mg: #41 tablets per 28 days.
10-20-30mg Two Week Starter Pack: #27 tablets per 14 days.
10-20-30mg 28-day Starter Pack: #55 tablets per 28 days.
10-20mg 28-day Starter Pack: #55 tablets per 28 days.
Approve the requested strength for 6 months as follows:
75mg XR: #1 per day.
30mg: #2 per day.
20mg: #2 per day.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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APREMILAST

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of Behcet's disease (ICD-10 M35.2) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The patient had a trial of or contraindication to ONE or more conservative clinical standard of care treatments (e.g., colchicine, topical corticosteroid [e.g., triamcinolone], oral corticosteroid [e.g., prednisolone])
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of Behcet's disease

If yes, **enter approval(s) by GPID or GPI-14 as follows:**
If the starter pack is requested for dosage titration, approve for #1 fill for the requested starter pack as follows:
10-20-30-75mg: #41 tablets per 28 days.
10-20-30mg Two Week Starter Pack: #27 tablets per 14 days.
10-20-30mg 28-day Starter Pack: #55 tablets per 28 days.
Approve the requested strength for 6 months as follows:
75mg XR: #1 per day.
30mg: #2 per day.

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.
Our guideline named **APREMILAST (Otezla, Otezla XR)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Plaque psoriasis (PsO: a type of skin condition)
- Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

If you have psoriatic arthritis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of psoriatic arthritis

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APREMILAST

INITIAL CRITERIA (CONTINUED)

If you have mild plaque psoriasis, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) one clinical standard of care agent: a conventional (standard) systemic (treatment that targets the entire body) medication (such as methotrexate, acitretin, cyclosporine) OR a conventional topical medication (such as topical corticosteroids [such as betamethasone dipropionate, clobetasol propionate])
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)]) for the treatment of mild plaque psoriasis
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to the requested medication
  - You have a static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) score of 2
  - You have a Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) score of 2 to 9

If you have moderate to severe plaque psoriasis, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)]) for the treatment of moderate to severe plaque psoriasis
- You meet ONE of the following:
  - You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor, or JAK (Janus kinase) inhibitor for the same indication

(Initial denial text continued on next page)

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APREMILAST

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You were previously stable on another biologic and are switching to the requested medication
- You have psoriasis covering 3 percent or more of body surface area (BSA)
- You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

If you have Behcet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You have tried or have a contraindication to (harmful for you to use) ONE or more conservative clinical standard of care treatments (such as colchicine, topical corticosteroid [such as triamcinolone], oral corticosteroid [such as prednisolone])
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Behcet's disease

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APREMILAST

RENEWAL CRITERIA

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PsA

If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
75mg XR: #1 per day.
30mg: #2 per day.
20mg: #2 per day.

If no, continue to #2.

Does the patient have a diagnosis of plaque psoriasis (PsO) (ICD-10 L40.0)?

If yes, continue to #3.
If no, continue to #5.

Is the patient's disease mild and the patient meets **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more OR a decrease in sPGA (static Physician Global Assessment) by at least a 2-point reduction from baseline
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of mild PsO

If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
75mg XR: #1 per day.
30mg: #2 per day.

If no, continue to #4.

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APREMILAST

RENEWAL CRITERIA (CONTINUED)

Is the patient's disease moderate to severe and the patient meets **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Zoryve (roflumilast)]) for the treatment of moderate to severe PsO

If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
75mg XR: #1 per day.
30mg: #2 per day.
20mg: #2 per day.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient have a diagnosis of Behcet's disease (ICD-10 M35.2) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms and meet **ALL** of the following criteria?
- The patient has achieved or maintained clinical benefit compared to baseline (e.g., pain scores, number of ulcers)
- The requested medication will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of Behcet's disease

If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
75mg XR: #1 per day.
30mg: #2 per day.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APREMILAST (Otezla, Otezla XR)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Plaque psoriasis (PsO: a type of skin condition)
- Behcet's disease (a type of inflammation disorder) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

(Renewal denial text continued on next page)

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APREMILAST

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of psoriatic arthritis

If you have mild plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more OR a decrease in static Physician Global Assessment (sPGA: a measure used to evaluate severity of the disease) by at least a 2-point reduction from baseline
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)]) for the treatment of mild plaque psoriasis

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Zoryve (roflumilast)]) for the treatment of moderate to severe plaque psoriasis

If you have Behcet's disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, renewal also requires:
- You have achieved or maintained clinical benefit compared to baseline (such as an improvement in pain scores, number of ulcers)
- You will NOT use the requested medication concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Behcet's disease

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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APREMILAST

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Otezla/Otezla XR.

REFERENCES

Otezla/Otezla XR [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; August 2025.

Created: 04/14
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APREPITANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APREPITANT	EMEND		40344	GPI-14 (50280020001930)	

GUIDELINES FOR USE

Is the request for **ONE** of the following?
- Prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin
- Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have a contraindication to or is unable to swallow aprepitant capsules?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APREPITANT (Emend)** requires the following rule(s) be met for approval:
The request is for ONE of the following:
- Prevention of acute (short-term) and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin (cancer treatment that causes nausea and vomiting)
- Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) (cancer treatment that causes nausea and vomiting)

You have a contraindication to (harmful for you to use) or are unable to swallow aprepitant capsules

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emend.

REFERENCES

Emend [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; November 2019.

Created: 05/26
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

APROCITENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APROCITENTAN	TRYVIO	49465		GPI-10 (3618001000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist, nephrologist, or endocrinologist
- The patient's blood pressure is NOT controlled on at least three anti-hypertensive agents of different pharmacologic classes (e.g., an angiotensin receptor blocker [e.g., valsartan], a calcium channel blocker [e.g., amlodipine]), with at least one being a diuretic (e.g., hydrochlorothiazide), at maximally tolerated doses for at least 4 weeks
- The patient does NOT have resistant hypertension due to white coat effect, medical inertia, or poor therapeutic adherence
- The patient had a trial of or contraindication to ONE of the following clinical standard of care agent: spironolactone, eplerenone

If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APROCITENTAN (Tryvio)** requires the following rule(s) be met for approval:

- You have hypertension (high blood pressure)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)
- Your blood pressure is NOT controlled on at least three anti-hypertensive medications (medications used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine]), with at least one being a diuretic (such as hydrochlorothiazide), at maximally tolerated doses for at least 4 weeks
- You do NOT have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), or poor therapeutic adherence (not keeping up with therapy)
- You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medication: spironolactone, eplerenone

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APROCITENTAN

RENEWAL CRITERIA

Does the patient have a diagnosis of hypertension (ICD-10 I10) **AND** meet the following criterion?
The patient continues to benefit from the medication

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APROCITENTAN (Tryvio)** requires the following rule(s) be met for renewal:
You have hypertension (high blood pressure)
You continue to benefit from Tryvio

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tryvio.

REFERENCES

Tryvio [Prescribing Information]. Radnor, PA: Idorsia Pharmaceuticals US Inc.; April 2025.

Created: 05/24
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ARIMOCLOMOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ARIMOCLOMOL CITRATE	MIPLYFFA	49879		GPI-10 (6200000320)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
Therapy is prescribed by or in consultation with a neurologist or geneticist
Miplyffa will be used in combination with miglustat (Zavesca)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3 per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ARIMOCLOMOL (Miplyffa)** requires the following rule(s) be met for approval:
You have Niemann-Pick disease type C (NPC: a type of genetic condition)
You are 2 years of age or older
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or geneticist (a doctor who treats gene disorders)
Miplyffa will used in combination with miglustat (Zavesca)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ARIMOCLOMOL

RENEWAL CRITERIA

Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?
The patient has experienced improvement or a slowing of disease progression

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ARIMOCLOMOL (Miplyffa)** requires the following rule(s) be met for renewal:
You have Niemann-Pick disease type C (NPC: a type of genetic condition)
You have shown improvement or a slowing of disease progression

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Miplyffa.

REFERENCES

Miplyffa [Prescribing Information]. Celebration, FL: Zevra Therapeutics, Inc.; September 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 10/24
Client Approval: 10/24
P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASCIMINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASCIMINIB HYDROCHLORIDE	SCEMBLIX	47647		GPI-10 (2153180610)	

GUIDELINES FOR USE

Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) (ICD-10 Group C92.1) **AND** meets the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient's cancer newly diagnosed (e.g., starting or previously started Scemblix treatment at the time of diagnosis)?

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
20mg: #2 per day.
40mg: #2 per day.

If no, continue to #3.

Does the patient's cancer have the T315I mutation **AND** meets the following criterion?
The patient had a mutational analysis prior to initiation of therapy; AND Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
40mg: #8 per day.
100mg: #4 per day.

If no, continue to #4.

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ASCIMINIB

GUIDELINES FOR USE (CONTINUED)

Has the patient been previously treated **AND** meets the following criterion?
The patient had a mutational analysis prior to initiation of therapy; AND Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
20mg: #2 per day.
40mg: #2 per day.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASCIMINIB (Scemblix)** requires the following rule(s) be met for approval:
You have Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer) in chronic phase (CP)
You are 18 years of age or older
You meet ONE of the following:
- Your cancer is newly diagnosed (such as you are starting or previously started Scemblix treatment at the time your condition was identified)
- Your cancer has the T315I mutation (abnormal change in a type of gene); you had a mutational analysis (a type of lab test) prior to the start of therapy; AND Scemblix is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on the profile for the breakpoint cluster region-Abelson murine leukemia 1 (BCR-ABL1: a type of gene) mutation
- You have been previously treated AND you had a mutational analysis prior to the start of therapy and Scemblix is appropriate based on the NCCN guideline table for treatment recommendations based on the profile for the BCR-ABL1 mutation

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASCIMINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Scemblix.

REFERENCES

Scemblix [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Co.; October 2024.

Created: 02/22
Effective: 08/11/25 Client Approval: 07/25 P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASFOTASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASFOTASE ALFA	STRENSIQ	42649		GPI-10 (3090561000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) (ICD-10 E83.39) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient was 6 months of age or younger at hypophosphatasia (HPP) onset

If yes, continue to #2.
If no, continue to #4.

Is the patient positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing?

If yes, continue to #7.
If no, continue to #3.

Does the patient meet at least **TWO** of the following criteria?
- The patient has a serum alkaline phosphatase (ALP) level below the normal range for patient age
- The patient has an elevated serum pyridoxal-5'-phosphate (PLP) level AND has not received vitamin B6 supplementation in the previous week
- The patient has a urine phosphoethanolamine (PEA) level above the normal range for patient age
- The patient has radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, widened growth plates, areas of radiolucency or sclerosis)
- The patient has at least TWO of the following:
  - Rachitic chest deformity
  - Craniosynostosis (premature closure of skull bones)
  - Delay in skeletal growth resulting in delay of motor development
  - History of vitamin B6 dependent seizures
  - Nephrocalcinosis or history of elevated serum calcium
  - History or presence of non-traumatic postnatal fracture and delayed fracture healing

If yes, continue to #7.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of juvenile-onset hypophosphatasia (HPP) (ICD-10 E83.39) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an endocrinologist
The patient was 18 years of age or younger at hypophosphatasia (HPP) onset

If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing?

If yes, continue to #7.
If no, continue to #6.

Does the patient meet at least **TWO** of the following criteria?
The patient has a serum alkaline phosphatase (ALP) level below the normal range for patient age
The patient has an elevated serum pyridoxal-5'-phosphate (PLP) level AND has not received vitamin B6 supplementation in the previous week
The patient has a urine phosphoethanolamine (PEA) level above the normal range for patient age
The patient has a radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, osteomalacia, widened growth plates, areas of radiolucency or sclerosis)
The patient has at least TWO of the following:
Rachitic deformities (rachitic chest, bowed legs, knock-knees)
Premature loss of primary teeth prior to 5 years of age
Delay in skeletal growth resulting in delay of motor development
History or presence of non-traumatic fractures or delayed fracture healing

If yes, continue to #7.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ANY** of the following criteria?
- The patient is currently receiving treatment with a bisphosphonate (e.g., Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])
- The patient's serum calcium or phosphate level is below the normal range
- The patient has a treatable form of rickets

If yes, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline

If no, **approve for 6 months by HICL or GPI-10.**

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Perinatal/infantile-onset hypophosphatasia (HPP: a type of genetic condition)
- Juvenile-onset hypophosphatasia (HPP: a type of genetic condition)

If you have perinatal/infantile-onset hypophosphatasia, approval also requires:
- You were 6 months of age or younger at the onset of hypophosphatasia
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- You will NOT use Strensiq with a bisphosphonate (such as Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])
- Your serum (blood) calcium and phosphate levels are NOT below the normal range
- You do NOT have a treatable form of rickets (type of bone condition in children)

(Initial denial text continued on next page)

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You are positive for a tissue non-specific alkaline phosphatase (TNSALP: a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing
- You meet at least TWO of the following:
  - Your serum alkaline phosphatase (type of enzyme) level is below the normal range for your age
  - Your serum pyridoxal-5'-phosphate (PLP: type of lab test) level is elevated AND you have not received vitamin B6 supplementation in the previous week
  - Your urine phosphoethanolamine (PEA: type of lab) level is above the normal range for your age
  - You have radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), widened growth plates, areas of radiolucency (appearing dark/black on x-ray image) or sclerosis (hardening of an area)]
  - You have TWO or more of the following:
    - Rachitic chest deformity (chest bones are not normal)
    - Craniosynostosis (premature closure of skull bones)
    - Delay in skeletal growth resulting in delay of motor development
    - History of vitamin B6 dependent seizures
    - Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
    - History or presence of fracture after birth not due to injury or delayed fracture healing

(Initial denial text continued on next page)

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

If you have juvenile-onset hypophosphatasia, approval also requires:
You were 18 years of age or younger at the onset of hypophosphatasia
Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
You will NOT use Strensiq with a bisphosphonate (such as Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])
Your serum (blood) calcium and phosphate levels are NOT below the normal range
You do NOT have a treatable form of rickets (softening and weakening of bones in children, usually due to low vitamin D)
You meet ONE of the following:
You are positive for a tissue non-specific alkaline phosphatase (TNSALP: a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing
You meet at least TWO of the following:
Your serum alkaline phosphatase (type of enzyme) level is below the normal range for your age
Your serum pyridoxal-5'-phosphate (PLP: type of lab test) level is elevated AND you have not received vitamin B6 supplementation in the previous week
Your urine phosphoethanolamine (PEA: type of lab test) level is above the normal range for your age
You have radiographic evidence of hypophosphatasia [such as flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), osteomalacia (bone softening), widened growth plates, areas of radiolucency (appearing dark/black on x-ray image) or sclerosis (hardening of an area)]
You have TWO or more of the following:
Rachitic deformities (rachitic chest, bowed legs, knock-knees)
Premature loss of primary teeth prior to 5 years of age
Delay in skeletal growth leading to motor development delay
History or presence of fracture after birth not due to injury or delayed fracture healing

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASFOTASE ALFA

RENEWAL CRITERIA

During the last 6 months of treatment, has the patient experienced an improvement in the skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of the irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Is the patient currently receiving treatment with a bisphosphonate (e.g., Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate])?

If yes, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, **approve for 12 months by HICL or by GPI-10.**

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASFOTASE ALFA (Strensiq)** requires that the following rule(s) be met for renewal:
You have experienced an improvement in the skeletal characteristics (bones, teeth) of hypophosphatasia (HPP: type of genetic condition). Characteristics may include irregularity of the provisional zone of calcification (area on long bone for calcium build-up), physeal widening (area of bone that helps length growth), metaphyseal flaring (a narrow part of long bone grows), radiolucencies (appearing dark/black on x-ray image), patchy osteosclerosis (parts of abnormal hardening of bone), ratio of mid-diaphyseal cortex to bone thickness, gracile (slender) bones, bone formation and fractures.
You will NOT use Strensiq with a bisphosphonate (such as Boniva [ibandronate], Fosamax [alendronate], Actonel [risedronate]).

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASFOTASE ALFA

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Strensiq.

REFERENCES
Strensiq [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; July 2024.

Created: 11/15
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ASPARAGINASE ERWINIA-RYWN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASPARAGINASE ERWINIA-RYWN	RYLAZE	47474		GPI-10 (2125001060)	

GUIDELINES FOR USE

Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) or lymphoblastic lymphoma (LBL) (ICD-10 Group C83.5) and meet **ALL** of the following criteria?
The patient is 1 month of age or older
The patient has developed a hypersensitivity to E. coli-derived asparaginase
Rylaze will be used as a component of a multi-agent chemotherapeutic regimen

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ASPARAGINASE ERWINIA-RYWN (Rylaze)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Acute lymphoblastic leukemia (ALL: a type of blood cancer)
- Lymphoblastic lymphoma (LBL: a type of immune system cancer)

You are 1 month of age or older
You have developed a hypersensitivity (allergic reaction) to E.coli-derived asparaginase (an enzyme/protein that is from a type of bacteria)
Rylaze will be used as a component of a multi-agent chemotherapeutic regimen (treatment using multiple drugs)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rylaze.

REFERENCES

Rylaze [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2024.

Created: 10/21
Effective: 02/01/26 Client Approval: 04/25 P&T Approval:10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATEZOLIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATEZOLIZUMAB	TECENTRIQ	43408		GPI-10 (2135821500)	

GUIDELINES FOR USE

Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, continue to #6.

Is the patient's cancer stage II to IIIA and the patient meets **ALL** of the following criteria?
Tecentriq will be used as adjuvant treatment following resection and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
The patient has tumor(s) that express PD-L1 on at least 1% of tumor cells, as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Is the patient's cancer metastatic without an EGFR or ALK mutation and the patient meets **ONE** of the following criteria?
The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
The patient has tumor(s) that have high PD-L1 expression (PD-L1 stained at least 50% of tumor cells [TC at least 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering at least 10% of the tumor area [IC at least 10%]), as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

Is the patient's cancer metastatic with an ALK mutation **AND** the patient meets the following criterion?
The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #5.

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ATEZOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

Is the patient's cancer metastatic with an EGFR mutation **AND** the patient meets the following criterion?
The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have a diagnosis of metastatic non-squamous non-small cell lung cancer (NSq NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer does NOT have EGFR or ALK genomic tumor aberrations
Tecentriq will be used in combination with bevacizumab, paclitaxel, and carboplatin, OR in combination with paclitaxel protein-bound and carboplatin

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

Does the patient have a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) (ICD-10 Group C34) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #8.
If no, continue to #9.

Does the patient meet **ONE** of the following criteria?
Tecentriq will be used in combination with carboplatin and etoposide
Tecentriq will be used in combination with Zepzelca (lurbinectedin) AND the patient's disease has not progressed after first-line induction therapy with Tecentriq or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), carboplatin, and etoposide

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ATEZOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
The patient has NOT received prior systemic therapy
Tecentriq will be used in combination with bevacizumab

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #10.

Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
Tecentriq will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
The patient's cancer is BRAF V600 mutation-positive

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #11.

Does the patient have a diagnosis of unresectable or metastatic alveolar soft part sarcoma (ASPS) (ICD-10 C49.9) **AND** meet the following criterion?
The patient is 2 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #12.

Does the patient have a diagnosis of muscle invasive bladder cancer (MIBC) (ICD-10 Group C67) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Tecentriq will be used as adjuvant treatment after a cystectomy
The patient has circulating tumor DNA molecular residual disease (ctDNA MRD), as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ATEZOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATEZOLIZUMAB (Tecentriq)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Non-small cell lung cancer (NSCLC: a type of lung cancer)
- Metastatic non-squamous non-small cell lung cancer (NSq NSCLC: a type of lung cancer that has spread to other parts of the body)
- Extensive-stage small cell lung cancer (ES-SCLC: a type of lung cancer)
- Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be removed by surgery or has spread to other parts of the body)
- Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
- Unresectable or metastatic alveolar soft part sarcoma (ASPS: a type of soft tissue cancer that cannot be removed by surgery or has spread to other parts of the body)
- Muscle invasive bladder cancer (MIBC: a type of bladder cancer that has spread to the muscle)

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ATEZOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

If you have non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - Your cancer is stage II to IIIA; Tecentriq will be used as adjuvant (add-on) treatment following resection (removal of tissue or organ) and platinum-based chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin, oxaliplatin); AND your tumor(s) express programmed death-ligand 1 (PD-L1: type of protein) on at least 1% of tumor cells, as determined by a Food and Drug Administration (FDA)-authorized test
  - Your cancer is metastatic (has spread to other parts of the body) and you meet ONE of the following:
    - Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
    - Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND you have tumor(s) that have high programmed death-ligand 1 (PD-L1: type of protein) expression (PD-L1 stained at least 50% of tumor cells OR PD-L1 stained tumor-infiltrating immune cells covering at least 10% of the tumor area), as determined by a Food and Drug Administration (FDA) authorized test
    - Your cancer has an anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
    - Your cancer has an epidermal growth factor receptor (EGFR: a type of protein) mutation (abnormal change in a type of gene); your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

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ATEZOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

If you have metastatic non-squamous non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your cancer does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) genomic tumor abnormalities (type of abnormal gene)
- Tecentriq will be used in combination with bevacizumab, paclitaxel, and carboplatin OR in combination with paclitaxel protein-bound and carboplatin

If you have extensive-stage small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - Tecentriq will be used in combination with carboplatin and etoposide
  - Tecentriq will be used in combination with Zepzelca (lurbinectedin) AND your disease has not progressed (worsened) after first-line induction therapy (start of treatment) with Tecentriq or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), carboplatin, and etoposide

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
- You have NOT previously been treated with systemic therapy (treatment that targets the entire body)
- Tecentriq will be used in combination with bevacizumab

If you have unresectable or metastatic melanoma, approval also requires:
- Tecentriq will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
- Your cancer is BRAF V600 mutation (abnormal change in a type of gene)-positive

If you have unresectable or metastatic alveolar soft part sarcoma, approval also requires:
- You are 2 years of age or older

If you have muscle invasive bladder cancer, approval also requires:
- You are 18 years of age or older
- Tecentriq will be used as adjuvant (add-on) treatment after a cystectomy (bladder removal surgery)
- You have circulating tumor DNA molecular residual disease (ctDNA MRD: traces of cancer DNA in your body), as determined by a Food and Drug Administration (FDA)-authorized test

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ATEZOLIZUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tecentriq.

REFERENCES

Tecentriq [Prescribing Information]. South San Francisco, CA: Genentech Inc.; May 2026.

Created: 05/16
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATEZOLIZUMAB-HYALURONIDASE-TQJS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATEZOLIZUMAB-HYALURONIDASE-TQJS	TECENTRIQ HYBREZA	49873		GPI-10 (2199000205)	

GUIDELINES FOR USE

Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, continue to #6.

Is the patient's cancer stage II to IIIA and the patient meets **ALL** of the following criteria?
Tecentriq Hybreza will be used as adjuvant treatment following resection and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
The patient has tumor(s) that express PD-L1 on at least 1% of tumor cells, as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Is the patient's cancer metastatic without an EGFR or ALK mutation and the patient meets **ONE** of the following criteria?
The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
The patient has tumor(s) that have high PD-L1 expression (PD-L1 stained at least 50% of tumor cells [TC at least 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering at least 10% of the tumor area [IC at least 10%]), as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

Is the patient's cancer metastatic with an ALK mutation **AND** the patient meets the following criterion?
The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #5.

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GUIDELINES FOR USE (CONTINUED)

Is the patient's cancer metastatic with an EGFR mutation **AND** the patient meets the following criterion?
The patient has experienced disease progression during or following treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have a diagnosis of metastatic non-squamous non-small cell lung cancer (NSq NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer does NOT have EGFR or ALK genomic tumor aberrations
Tecentriq Hybreza will be used in combination with bevacizumab, paclitaxel, and carboplatin, OR in combination with paclitaxel protein-bound and carboplatin

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

Does the patient have a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) (ICD-10 Group C34) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #8.
If no, continue to #9.

Does the patient meet **ONE** of the following criteria?
Tecentriq Hybreza will be used in combination with carboplatin and etoposide
Tecentriq Hybreza will be used in combination with Zepzelca (lurbinectedin) AND the patient's disease has not progressed after first-line induction therapy with Tecentriq Hybreza or intravenous Tecentriq (atezolizumab), carboplatin, and etoposide

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has NOT received prior systemic therapy
Tecentriq Hybreza will be used in combination with bevacizumab

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #10.

Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Tecentriq Hybreza will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
The patient's cancer is BRAF V600 mutation-positive, as determined by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #11.

Does the patient have a diagnosis of unresectable or metastatic alveolar soft part sarcoma (ASPS) (ICD-10 C49.9) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #12.

Does the patient have a diagnosis of muscle invasive bladder cancer (MIBC) (ICD-10 Group C67) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Tecentriq Hybreza will be used as adjuvant treatment after a cystectomy
The patient has circulating tumor DNA molecular residual disease (ctDNA MRD), as determined by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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ATEZOLIZUMAB-HYALURONIDASE-TQJS

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATEZOLIZUMAB-HYALURONIDASE-TQJS (Tecentriq Hybreza)** requires the following rule(s) be met for approval:
You have ONE of the following:

- Non-small cell lung cancer (NSCLC: a type of lung cancer)
- Metastatic non-squamous non-small cell lung cancer (NSq NSCLC: a type of lung cancer that has spread to other parts of the body)
- Extensive-stage small cell lung cancer (ES-SCLC: a type of lung cancer)
- Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be completely removed by surgery or has spread to other parts of the body)
- Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
- Unresectable or metastatic alveolar soft part sarcoma (ASPS: a type of soft tissue cancer that cannot be completely removed by surgery or has spread to other parts of the body)
- Muscle invasive bladder cancer (MIBC: a type of bladder cancer that has spread to the muscle)

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GUIDELINES FOR USE (CONTINUED)

If you have non-small cell lung cancer, approval also requires:

You are 18 years of age or older

You meet ONE of the following:

Your cancer is Stage II to IIIA; Tecentriq Hybreza will be used as adjuvant treatment (additional treatment) following resection (removal of tissue or organ) and platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin); AND your tumor(s) express programmed death-ligand 1 (PD-L1: type of protein) on at least 1% of tumor cells, as determined by a Food and Drug Administration (FDA)-authorized test

Your cancer is metastatic (has spread to other parts of the body) and you meet ONE of the following:

Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND you have experienced disease progression (worsening) during or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

Your cancer does NOT have an epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene); AND you have tumors that have high programmed death-ligand 1 (PD-L1: type of protein) expression (PD-L1 stained at least 50% of tumor cells OR PD-L1 stained tumor-infiltrating immune cells covering at least 10% of the tumor area), as determined by a Food and Drug Administration (FDA)- authorized test

Your cancer has an anaplastic lymphoma kinase (ALK: a type of protein) mutation (abnormal change in a type of gene), and your disease has gotten worse during or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])

Your cancer has an epidermal growth factor receptor (EGFR: a type of protein) mutation (abnormal change in a type of gene), and your disease has gotten worse during or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

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ATEZOLIZUMAB-HYALURONIDASE-TQJS

GUIDELINES FOR USE (CONTINUED)

If you have metastatic non-squamous non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- Your cancer does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) genomic tumor abnormalities (type of abnormal gene)
- Tecentriq Hybreza will be used in combination with bevacizumab, paclitaxel, and carboplatin, OR in combination with paclitaxel protein-bound and carboplatin

If you have extensive-stage small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - Tecentriq Hybreza will be used in combination with carboplatin and etoposide
  - Tecentriq Hybreza will be used in combination with Zepzelca (lurbinectedin) AND your disease has not progressed (worsened) after first-line induction therapy (start of treatment) with Tecentriq Hybreza or intravenous (injection into the vein) Tecentriq (atezolizumab), carboplatin, and etoposide

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
- You are 18 years of age or older
- You have NOT previously been treated with systemic therapy (treatment that targets the entire body)
- Tecentriq Hybreza will be used in combination with bevacizumab

If you have unresectable or metastatic melanoma, approval also requires:
- You are 18 years of age or older
- Tecentriq Hybreza will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
- Your cancer is BRAF V600 mutation (abnormal change in a type of gene)-positive, as determined by a Food and Drug Administration (FDA)-approved test

If you have unresectable or metastatic alveolar soft part sarcoma, approval also requires:
- You are 18 years of age or older

If you have muscle invasive bladder cancer, approval also requires:
- You are 18 years of age or older
- Tecentriq Hybreza will be used as adjuvant (add-on) treatment after a cystectomy (bladder removal surgery)
- You have circulating tumor DNA molecular residual disease (ctDNA MRD: traces of cancer DNA in your body), as determined by a Food and Drug Administration (FDA)-authorized test

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ATEZOLIZUMAB-HYALURONIDASE-TQJS

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tecentriq Hybreza.

REFERENCES
Tecentriq Hybreza [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2026.

Created: 09/24
Effective: 6/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATOGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATOGEPANT	QULIPTA	47599		GPI-10 (6770101000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Qulipta is prescribed for the preventive treatment of migraines
- Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention

If yes, **approve for 6 months by HICL or GPI-10.**
If no, continue to #2.

Does the patient have a diagnosis of chronic migraines (ICD-10 Groups G43.7, G43.E) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Qulipta is prescribed for the preventive treatment of migraines
- Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ATOGEPANT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Episodic migraines (a type of headache)
- Chronic migraines (a type of headache)

If you have episodic migraines (0-14 headache days per month), approval also requires:
- You are 18 years of age or older
- Qulipta is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine (a type of headache) prevention

If you have chronic migraines (15 or more headache days per month), approval also requires:
- You are 18 years of age or older
- Qulipta is prescribed for the preventive treatment of migraines (a type of headache)
- You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine (a type of headache) prevention

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATOGEPANT

RENEWAL CRITERIA

Is the request for the preventive treatment of migraines **AND** the patient meets the following criterion?
- Qulipta will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine prevention

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Qulipta therapy
- The patient has experienced a reduction in migraine severity with Qulipta therapy
- The patient has experienced a reduction in migraine duration with Qulipta therapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATOGEPANT (Qulipta)** requires the following rule(s) be met for renewal:
The request is for the preventive treatment of migraines (a type of headache)
You will NOT use Qulipta concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet]) for migraine (a type of headache) prevention
You meet ONE of the following:
- You have experienced a decrease in migraine (a type of headache) or headache frequency of at least 2 days per month with Qulipta therapy
- You have experienced a decrease in migraine (a type of headache) severity with Qulipta therapy
- You have experienced a decrease in migraine (a type of headache) duration with Qulipta therapy

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATOGEPANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qulipta.

REFERENCES

Qulipta [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; September 2025.

Created: 10/21
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATORVASTATIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATORVASTATIN CALCIUM	ATORVALIQ		53672	GPI-14 (39400010101810)	

GUIDELINES FOR USE

Does the patient have a contraindication to or is unable to swallow atorvastatin oral tablets?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the patient also requesting a zero-dollar cost share exception (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

If yes, continue to #3.
If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20 mL per day.**

Does the patient meet **ALL** of the following criteria?
The patient is between 40 to 75 years old
The requested quantity is within the low to moderate intensity daily dosage of 10mg to 20mg
The patient is NOT concurrently taking any of the following secondary prevention medications for cardiovascular disease:
Aspirin/dipyridamole (Aggrenox)
Clopidogrel (Plavix)
Dipyridamole
Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
Prasugrel (Effient)
Ticagrelor (Brilinta)
Ticlopidine
Vorapaxar (Zontivity)

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #5 mL per day at zero copay.**

If no, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20 mL per day.**

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ATORVASTATIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATORVASTATIN (Atorvaliq)** requires the following rule(s) be met for approval:
You have a contraindication to (harmful for you to use) or are unable to swallow atorvastatin oral tablets
Requests for zero-dollar cost share also requires the following:
You are between 40 to 75 years old
The requested quantity is within the low to moderate intensity daily dosage of 10mg to 20mg
You are NOT concurrently (at the same time) taking any of the following secondary prevention medications for cardiovascular disease (heart disease):
Aspirin/dipyridamole (Aggrenox)
Clopidogrel (Plavix)
Dipyridamole
Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
Prasugrel (Effient)
Ticagrelor (Brilinta)
Ticlopidine
Vorapaxar (Zontivity)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Atorvaliq.

This guideline also applies to plans where the pharmacy benefit allows for coverage Atorvaliq at zero copay. The override criteria allow patient a zero copay by waiving the applicable cost-sharing to Atorvaliq, which is included in the MedImpact EHB Zero Dollar Copay List.

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ATORVASTATIN

REFERENCES

Atorvaliq [Prescribing Information]. Farmville, NC: CMP Pharma, Inc.; April 2024.
U.S. Preventive Services Task Force [Final Summary]. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication. Updated August 2022. Available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/statin-use-in-adults-preventive-medication. Accessed October 2025.
U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs. Accessed October 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ATRASENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ATRASENTAN HYDROCHLORIDE	VANRAFIA	50412		GPI-10 (5648250720)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient is at risk of rapid disease progression (e.g., urine protein-to-creatinine ratio [UPCR] of at least 1.5 g/g)
Therapy is prescribed by or in consultation with a nephrologist
The patient's diagnosis is confirmed by a biopsy
The patient has proteinuria of at least 0.5 g/day
The patient has an eGFR of at least 30 mL/min/1.73 m(2)
The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes

If yes, **approve for 9 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATRASENTAN (Vanrafia)** requires the following rule(s) be met for approval:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You are 18 years of age or older
You are at risk of rapid disease progression (such as a urine protein-to-creatinine ratio [UPCR: a test that measures the amount of protein in urine] of at least 1.5 g/g)
Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
Your diagnosis is confirmed by a biopsy (removal of cells or tissue for examination)
You have proteinuria (high levels of protein in the urine) of at least 0.5 g/day
You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
(Initial denial text continued on next page)

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ATRASENTAN

INITIAL CRITERIA (CONTINUED)

You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ATRASENTAN

RENEWAL CRITERIA

Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ONE** of the following criteria?
The patient has had a reduction in proteinuria
The patient has improved or stable kidney function compared to baseline

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ATRASENTAN (Vanrafia)** requires the following rule(s) be met for renewal:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You meet ONE of the following:
- You have had a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)
- You have improved or stable kidney function compared to baseline (before starting Vanrafia)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vanrafia.

REFERENCES

Vanrafia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVACINCAPTAD PEGOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVACINCAPTAD PEGOL SODIUM/PF	IZERVAY	49130		GPI-10 (8645602010)	

GUIDELINES FOR USE

Does the patient have a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) (ICD-10 Group H35.31)?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.2mL per 21 days.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVACINCAPTAD PEGOL (Izervay)** requires the following rule(s) be met for approval:
You have geographic atrophy (GA: an advanced type of eye disease) due to age-related macular degeneration (AMD: a type of eye disease)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Izervay.

REFERENCES

Izervay [Prescribing Information]. Parsippany, NJ: IVERIC bio, Inc.; August 2023.

Created: 10/23
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVACOPAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVACOPAN	TAVNEOS	47626		GPI-10 (8580551000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]) (ICD-10 I77.82) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist or nephrologist
The patient is ANCA seropositive (anti-PR3 or anti-MPO)
Tavneos will be used as adjunctive therapy in combination with standard therapy including glucocorticoids (e.g., methylprednisolone, prednisone)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6 per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVACOPAN (Tavneos)** requires the following rule(s) be met for approval:
You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]: conditions that affect the blood vessels)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
You are ANCA seropositive for anti-PR3 or anti-MPO (a type of lab test)
Tavneos will be used as adjunctive (add-on) therapy in combination with standard therapy including glucocorticoids (such as methylprednisolone, prednisone)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVACOPAN

RENEWAL CRITERIA

Does the patient have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]) (ICD-10 I77.82) **AND** meet the following criterion?
The patient continues to benefit from therapy (e.g., improvement of clinical manifestations, if renal vasculitis - improvement in eGFR and proteinuria values, reduction of corticosteroid dose without disease flares)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVACOPAN (Tavneos)** requires the following rule(s) be met for renewal:
You have severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (inflammation of blood vessels) (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]: conditions that affect the blood vessels)
You continue to benefit from the medication (such as improvement of clinical symptoms, if renal vasculitis [inflammation of blood vessels in the kidneys] - improvement in estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] and proteinuria [increased levels of protein in the urine] values, reduction of corticosteroid [a type of drug used to treat inflammation] dose without disease flares)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tavneos.

REFERENCES

Tavneos [Prescribing Information]. Thousand Oaks, CA: ChemoCentryx, Inc.; June 2024.

Created: 02/22
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVALGLUCOSIDASE ALFA-NGPT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVALGLUCOSIDASE ALFA-NGPT	NEXVIAZYME	47521		GPI-10 (3090772255)	

GUIDELINES FOR USE

Does the patient have a diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (ICD-10 E74.02) **AND** meet the following criterion?
The patient is 1 year of age or older

If yes, **approve for lifetime by HICL or GPI-10 with a fill limit of #2 fills per 28 days.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVALGLUCOSIDASE ALFA-NGPT (Nexviazyme)** requires the following rule(s) be met for approval:
You have late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (a type of genetic disorder)
You are 1 year of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nexviazyme.

REFERENCES

Nexviazyme [Prescribing Information]. Cambridge, MA: Genzyme Corporation; September 2023.

Created: 10/21
Effective: 05/13/26 Client Approval: 05/26 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVAPRITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVAPRITINIB	AYVAKIT	46291		GPI-10 (2149000900)	

GUIDELINES FOR USE

Does the patient have a diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, continue to #2.

Does the patient have a diagnosis of advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) (ICD-10 D47.02, C96.21; Group C94.3), **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, continue to #3.

Does the patient have a diagnosis of indolent systemic mastocytosis (ISM) (ICD-10 D47.02) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day**.
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVAPRITINIB (Ayvakit)** requires the following rule(s) be met for approval:
You have ONE of the following:
Unresectable or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that cannot be removed through surgery or has spread to other parts of the body)
Advanced systemic mastocytosis (AdvSM: a type of blood disorder), including aggressive systemic mastocytosis (ASM: a type of blood disorder), systemic mastocytosis with an associated hematological neoplasm (SM-AHN: a type of blood disorder), or mast cell leukemia (MCL: a type of blood cancer)
Indolent systemic mastocytosis (ISM: a type of blood disorder)
(Denial text continued on next page)

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AVAPRITINIB

GUIDELINES FOR USE (CONTINUED)

If you have unresectable or metastatic gastrointestinal stromal tumor, approval also requires:
You are 18 years of age or older
You have a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations (abnormal change in a type of gene)

If you have advanced systemic mastocytosis, approval also requires:
You are 18 years of age or older

If you have indolent systemic mastocytosis, approval also requires:
You are 18 years of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ayvakit.

REFERENCES

Ayvakit [Prescribing Information]. Cambridge, MA: Blueprint Medicines Corporation; November 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVATROMBOPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVATROMBOPAG MALEATE	DOPTELET, DOPTELET SPRINKLE	44942		GPI-10 (8240501020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of thrombocytopenia in chronic liver disease and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient is scheduled to undergo a procedure 10 to 13 days following the initiation of Doptelet therapy
- The patient has a platelet count of less than 50 x 10^9/L
- Doptelet will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Promacta [eltrombopag])

If yes, **approve by HICL or GPI-10 for 1 fill with a quantity limit of #15.**
If no, continue to #2.

Does the patient have a diagnosis of persistent or chronic immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
- The patient is 1 year of age or older
- The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: a corticosteroid or IV immunoglobulin, OR had an insufficient response to a splenectomy
- The patient has a platelet count of less than 30 x 10^9/L, OR has a platelet count of less than 50 x 10^9/L and had a prior bleeding event
- The requested medication will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])

If yes, **approve the requested strength for 2 months by GPID or GPI-14 with a quantity limit of #2 per day.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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AVATROMBOPAG

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVATROMBOPAG (Doptelet, Doptelet Sprinkle)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Thrombocytopenia (a type of blood disorder) in chronic (long-term) liver disease
- Persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)

If you have thrombocytopenia in chronic liver disease, approval also requires:
- You are 18 years of age or older
- You are scheduled to undergo a procedure 10 to 13 days after starting Doptelet therapy
- You have a platelet (a type of blood cell) count of less than 50 x 10^9/L
- You will NOT use Doptelet concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag])

If you have persistent or chronic immune thrombocytopenia, approval also requires:
- You are 1 year of age or older
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: a corticosteroid or intravenous (injection into the vein) immunoglobulin, OR you did not have a good enough response to a splenectomy (spleen removal)
- You have a platelet (a type of blood cell) count of less than 30 x 10^9/L, OR you have a platelet (a type of blood cell) count of less than 50 x 10^9/L and had a prior bleeding event
- You will NOT use the requested medication concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])

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AVATROMBOPAG

RENEWAL CRITERIA

NOTE: For the diagnosis of thrombocytopenia in chronic liver disease, please refer to the Initial Criteria section.

Does the patient have a diagnosis of persistent or chronic immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
- The patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events
- The requested medication will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVATROMBOPAG (Doptelet, Doptelet Sprinkle)** requires the following rule(s) be met for renewal:
- You have persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)
- You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Doptelet) OR a decrease in bleeding events
- You will NOT use the requested medication concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Nplate [romiplostim], Promacta [eltrombopag], Alvaiz [eltrombopag])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Doptelet/Doptelet Sprinkle.

REFERENCES

Doptelet/Doptelet Sprinkle [Prescribing Information]. Morrisville, NC: Sobi, Inc.; July 2025.

Created: 08/18
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVELUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVELUMAB	BAVENCIO	44170		GPI-10 (2135822000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic Merkel cell carcinoma (MCC) (ICD-10 C7B.1; Group C4A) **AND** meet the following criterion?
The patient is 12 years or older

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #80mL per 28 days.**

If no, continue to #2.

Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (UC) (ICD- 10 Groups C65, C66, C67, C68) and meet **ONE** of the following criteria?
The patient has disease progression during or following platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
The patient does not have disease progression with first-line platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin), AND Bavencio will be used as first-line maintenance treatment

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #80mL per 28 days.**

If no, continue to #3.

Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
Bavencio will be used in combination with Inlyta (axitinib)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #80mL per 28 days.**

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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AVELUMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

Our guideline named **AVELUMAB (Bavencio)** requires the following rules be met for approval:
You have ONE of the following:
- Metastatic Merkel cell carcinoma (MCC: a type of skin cancer)
- Locally advanced or metastatic (disease that has spread) urothelial carcinoma (UC: type of urinary system cancer)
- Advanced renal cell carcinoma (RCC: a type of kidney cancer)

If you have metastatic Merkel Cell Carcinoma, approval also requires:
- You are 12 years of age or older

If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:
- Your disease has worsened during or after platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
- Your disease has worsened within 12 months of neoadjuvant (treatment given before a main treatment) or adjuvant treatment (add-on to a main treatment) with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
- Your disease has not worsened with first-line platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin), AND Bavencio will be used as first-line maintenance treatment

If you have advanced renal cell carcinoma, approval also requires:
- Bavencio will be used in combination with Inlyta (axitinib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Bavencio.

REFERENCES
Bavencio [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; November 2024.

Created: 04/17
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AVUTOMETINIB-DEFACTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVUTOMETINIB-DEFACTINIB	AVMAPKI-FAKZYNJA	50549		GPI-10 (2199000207)	

GUIDELINES FOR USE

Does the patient have a diagnosis of recurrent low-grade serous ovarian cancer (LGSOC) (ICD-10 Group C56) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer has a KRAS mutation
The patient has received prior systemic therapy (e.g., platinum-based chemotherapy)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #66 per 28 days.** If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AVUTOMETINIB-DEFACTINIB (Avmapki-Fakzynja)** requires the following rule(s) be met for approval:
You have recurrent low-grade serous ovarian cancer (LGSOC: a type of reproductive system cancer that has returned)
You are 18 years of age or older
Your cancer has a KRAS mutation (a type of abnormal gene)
You have received prior systemic therapy (such as platinum-based chemotherapy [a type of therapy to treat cancer])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Avmapki-Fakzynja.

REFERENCES

Avmapki-Fakzynja [Prescribing Information]. Needham, MA: Verastem, Inc.; May 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AXATILIMAB-CSFR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AXATILIMAB-CSFR	NIKTIMVO	49817		GPI-10 (9939261010)	

GUIDELINES FOR USE

Does the patient have a diagnosis of chronic graft-versus-host disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
The patient weighs at least 40kg (88 lbs)
The patient has failed at least TWO lines of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to Jakafi (ruxolitinib)
Niktimvo will NOT be used concurrently with Jakafi (ruxolitinib), Rezurock (belumosudil), or Imbruvica (ibrutinib)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AXATILIMAB-CSFR (Niktimvo)** requires the following rule(s) be met for approval:
You have chronic graft-versus-host disease (cGVHD: a type of long-term immune disorder)
You weigh at least 40 kilograms (88 pounds)
You have failed at least TWO lines of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to (harmful for you to use) Jakafi (ruxolitinib)
You will NOT use Niktimvo concurrently (at the same time) with Jakafi (ruxolitinib), Rezurock (belumosudil), or Imbruvica (ibrutinib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Niktimvo.

REFERENCES
Niktimvo [Prescribing Information]. Wilmington, DE: Incyte Corporation; January 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AXITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AXITINIB	INLYTA	38446		GPI-10 (2133501300)	

GUIDELINES FOR USE

Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ONE** of the following criteria?
Inlyta will be used in combination with avelumab (Bavencio)
Inlyta will be used in combination with pembrolizumab (Keytruda)
The patient has tried at least one systemic therapy for RCC (e.g., Nexavar [sorafenib], Torisel [temsirolimus], Sutent [sunitinib], Votrient [pazopanib], Avastin [bevacizumab] in combination with interferon)

If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
1 mg: #6 per day.
5 mg: #4 per day.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AXITINIB (Inlyta)** requires the following rule(s) be met for approval:
You have advanced renal cell carcinoma (RCC: a type of kidney cancer)
You meet ONE of the following:
Inlyta will be used in combination with avelumab (Bavencio)
Inlyta will be used in combination with pembrolizumab (Keytruda)
You have tried at least one systemic therapy (treatment that targets the entire body) for renal cell carcinoma (such as Nexavar [sorafenib], Torisel [temsirolimus], Sutent [sunitinib], Votrient [pazopanib], Avastin [bevacizumab] in combination with interferon)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inlyta.

REFERENCES

Inlyta [Prescribing Information]. New York, NY: Pfizer; July 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AZACITIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AZACITIDINE	ONUREG		48545 48540	GPI-14 (21300003000330, 21300003000320)	

GUIDELINES FOR USE

Does the patient have a diagnosis of acute myeloid leukemia (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy
- The patient is NOT able to complete intensive curative therapy

If yes, **approve for 12 months for all strengths by GPID or GPI-14 with a quantity limit of #14 per 28 days.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AZACITIDINE (Onureg)** requires the following rule(s) be met for approval:
- You have acute myeloid leukemia (AML: type of blood and bone marrow cancer)
- You are 18 years of age or older
- You have achieved first complete remission (CR: signs or symptoms of cancer have disappeared) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy (medications for cancer)
- You are NOT able to complete intensive curative therapy (treatment to cure the disease)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Onureg.

REFERENCES
Onureg [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; October 2022.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AZELAIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AZELAIC ACID	AZELEX	07471		GPI-10 (9005000510)	FDB: BRAND = AZELEX

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of acne vulgaris (ICD-10 L70.0) and meet **ALL** of the following criteria?
Azelex will NOT be used concurrently with other single source brand acne agents (e.g., Aklief, Cabtreo, Winlevi)
The patient had a trial of or contraindication to THREE preferred generic topical agents for the treatment of acne (e.g., azelaic acid 15% gel, benzoyl peroxide, topical clindamycin)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AZELAIC ACID (Azelex)** requires the following rule(s) be met for approval:
You have acne vulgaris (a type of skin condition)
Azelex will NOT be used concurrently (at the same time) with other acne therapies that are only available as brand name (such as Aklief, Cabtreo, Winlevi)
You have tried or have a contraindication to (harmful for you to use) THREE preferred generic topical medications for the treatment of acne (such as azelaic acid 15% gel, benzoyl peroxide, topical clindamycin)

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AZELAIC ACID

RENEWAL CRITERIA

Does the patient have a diagnosis of acne vulgaris (ICD-10 L70.0) **AND** meet the following criterion?
Azelex will NOT be used concurrently with other single source brand acne agents (e.g., Aklief, Cabtreo, Winlevi)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AZELAIC ACID (Azelex)** requires the following rule(s) be met for renewal:
You have acne vulgaris (a type of skin condition)
Azelex will NOT be used concurrently (at the same time) with other acne therapies that are only available as brand name (such as Aklief, Cabtreo, Winlevi)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Azelex.

REFERENCES

Azelex [Prescribing Information]. Malvern, PA: Almirall, LLC; February 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

AZTREONAM INHALED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AZTREONAM LYSINE	CAYSTON	36792		GPI-10 (1614001040)	

GUIDELINES FOR USE

Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
- The patient is 7 years of age or older
- The patient has a lung infection with a Gram-negative species (such as *Pseudomonas aeruginosa*; not *Staphylococcus aureus* because it is not a Gram-negative species)

If yes, **approve for 12 months by HICL or GPI-10 for 6 fills with a quantity limit of #84 vials per 56 days.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AZTREONAM INHALED (Cayston)** requires the following rule(s) be met for approval:
- You have cystic fibrosis (CF: a type of lung disorder)
- You are 7 years of age or older
- You have a lung infection with a Gram-negative bacterial species (a type of bacteria such as *Pseudomonas aeruginosa*)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cayston.

REFERENCES

Cayston [Prescribing Information]. Foster City, CA. Gilead Sciences, Inc.; November 2019.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BACLOFEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BACLOFEN	OZOBAX, OZOBAX DS, BACLOFEN		64209 54913	GPI-14 (75100010002070, 75100010002075)	
BACLOFEN	FLEQSUVY, BACLOFEN		51885	GPI-14 (75100010001825)	

GUIDELINES FOR USE

Is the request for Ozobax (baclofen) or Ozobax DS (baclofen) **AND** the patient meets the following criterion?
The patient has a contraindication to or is unable to swallow baclofen oral tablets

If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
5mg/5mL: #80mL per day.
10mg/5mL: #40mL per day.

If no, continue to #2.

Is the request for Fleqsuvy (baclofen) **AND** the patient meets the following criterion?
The patient has a contraindication to or is unable to swallow baclofen oral tablets

If yes**, approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BACLOFEN (Ozobax, Ozobax DS, Fleqsuvy)** requires the following rule(s) be met for approval:
A. You have a contraindication to (harmful for you to use) or are unable to swallow baclofen oral tablets

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BACLOFEN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ozobax, Ozobax DS, and Fleqsuvy.

REFERENCES

Ozobax [Prescribing Information]. Athens, GA: Metacel Pharmaceuticals, LLC; May 2020.
Ozobax DS [Prescribing Information]. Athens, GA: Metacel Pharmaceuticals, LLC; October 2023.
Fleqsuvy [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; April 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BARICITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BARICITINIB	OLUMIANT	44296		GPI-10 (6660301000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Olumiant will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
- The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - [**Note:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
  If no, continue to #2.

Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

If yes, **do not approve**. [**NOTE:** This indication is for hospital use only.]
DENIAL TEXT: See initial denial text at the end of the guideline.

If no, continue to #3.

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BARICITINIB

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of severe alopecia areata (ICD-10 Group L63) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has had at least 50% scalp hair loss, as measured by the Severity of Alopecia Tool (SALT), for more than 6 months
- Olumiant will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Litfulo (ritlecitinib)], PDE-4 inhibitor) for the treatment of alopecia areata

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Severe alopecia areata (a type of hair loss)

(Initial denial text continued on next page)

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BARICITINIB

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Olumiant concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

If you have severe alopecia areata, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have had at least 50 percent scalp hair loss, as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool), for more than 6 months
- You will NOT use Olumiant concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Litfulo (ritlecitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata (a type of hair loss)

NOTE: Olumiant will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults.

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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BARICITINIB

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Olumiant will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - [**Note:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
  If no, continue to #2.

Does the patient have a diagnosis of severe alopecia areata (ICD-10 Group L63) and meet **ALL** of the following criteria?
- The patient has had improvement while on therapy (e.g., scalp hair coverage)
- Olumiant will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Litfulo (ritlecitinib)], PDE-4 inhibitor) for the treatment of alopecia areata

  If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
  If no, do not approve.
  DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BARICITINIB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Severe alopecia areata (a type of hair loss)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Olumiant concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor (TNF) blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

If you have severe alopecia areata, renewal also requires:
- You have experienced improvement while on therapy (such as scalp hair coverage)
- You will NOT use Olumiant concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Litfulo (ritlecitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata (a type of hair loss)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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BARICITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Olumiant.

REFERENCES

Olumiant [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; June 2022.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BAXDROSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BAXDROSTAT	BAXFENDY	51327		GPI-10 (3613002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?

The patient is 18 years of age or older

Therapy is prescribed by or in consultation with a cardiologist, nephrologist, or endocrinologist

The patient's blood pressure is NOT controlled on at least three anti-hypertensive agents of different pharmacologic classes (e.g., an angiotensin receptor blocker [e.g., valsartan], a calcium channel blocker [e.g., amlodipine]), with at least one being a diuretic (e.g., hydrochlorothiazide), at maximally tolerated doses for at least 4 weeks

The patient does NOT have resistant hypertension due to white coat effect, medical inertia, poor therapeutic adherence, or secondary causes of hypertension (except primary aldosteronism and sleep apnea)

The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: spironolactone, eplerenone

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: Our guideline named **BAXDROSTAT (Baxfendy)** requires the following rule(s) be met for approval:

You have hypertension (high blood pressure)

You are 18 years of age or older

Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)

Your blood pressure is NOT controlled on at least three anti-hypertensive medications (medications used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine]), with at least one being a diuretic (such as hydrochlorothiazide), at maximally tolerated doses for at least 4 weeks

You do NOT have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), poor therapeutic adherence (not keeping up with therapy), or secondary causes of hypertension (except primary aldosteronism [a type of hormone disorder] and sleep apnea [a type of sleep condition with difficulty breathing])

You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: spironolactone, eplerenone

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BAXDROSTAT

RENEWAL CRITERIA

Does the patient have a diagnosis of hypertension (ICD-10 I10) **AND** meet the following criterion?
The patient has had blood pressure reduction or achieved blood pressure goal

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: Our guideline named **BAXDROSTAT (Baxfendy)** requires the following rule(s) be met for renewal:
You have hypertension (high blood pressure)
You have had blood pressure reduction (decrease) or achieved blood pressure goal

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Baxfendy.

REFERENCES

Baxfendy [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.

Created: 05/26
Effective: 08/01/26 DMC Approval: 07/21/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEDAQUILINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEDAQUILINE FUMARATE	SIRTURO	39895		GPI-10 (0900001510)	

GUIDELINES FOR USE

Does the patient have a diagnosis of pulmonary tuberculosis (TB) (ICD-10 Group A15)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have an isolate of *Mycobacterium tuberculosis* that is resistant to rifampin and isoniazid?

If yes, continue to #3.
If no, continue to #5.

Is the patient 2 years of age or older **AND** meets the following criterion?
Sirturo will be used in combination with at least 3 other antibiotics

If yes, **approve for a total of 24 weeks by GPID or GPI-14 as follows:**
FIRST APPROVAL: Approve the requested strength for 4 weeks as follows:
20mg: #340 per 28 days.
100mg: #68 per 28 days.
SECOND APPROVAL: Approve the requested strength for 20 weeks (total fill count 5) as follows (please enter a start date of 3 WEEKS AFTER the START date of the first approval):
20mg: #120 per 28 days.
100mg: #24 per 28 days.

If no, continue to #4.

Is the patient 18 years of age or older **AND** meets the following criterion?
Sirturo will be used in combination with pretomanid and linezolid

If yes, **approve the 100mg strength for a total of 26 weeks by GPID or GPI-14 as follows:**
FIRST APPROVAL: Approve for 4 weeks with a quantity limit of #68 per 28 days.
SECOND APPROVAL: Approve for 22 weeks (total fill count 6) with a quantity limit of #24 per 28 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval.)

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BEDAQUILINE

GUIDELINES FOR USE (CONTINUED)

Does the patient have an isolate of *Mycobacterium tuberculosis* that is resistant to isoniazid, rifampin, a fluoroquinolone, and an aminoglycoside?

If yes, continue to #6.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient meet **ALL** of the following criteria?
The patient is 18 years of age or older
Sirturo will be used in combination with pretomanid and linezolid

If yes, **approve the 100mg strength for a total of 26 weeks by GPID or GPI-14 as follows:**
FIRST APPROVAL: Approve for 4 weeks with a quantity limit of #68 per 28 days.
SECOND APPROVAL: Approve for 22 weeks (total fill count 6) with a quantity limit of #24 per 28 days. (Please enter a start date of 3 WEEKS AFTER the START date of the first approval.)

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEDAQUILINE (Sirturo)** requires the following rule(s) be met for approval:
You have pulmonary tuberculosis (TB: a type of lung infection)
You meet ONE of the following:
- You have an isolate of *Mycobacterium tuberculosis* (a type of bacterium) that is resistant to rifampin and isoniazid; you are 2 years of age or older; and you will use Sirturo in combination with at least 3 other antibiotics
- You have an isolate of *Mycobacterium tuberculosis* that is resistant to rifampin and isoniazid; you are 18 years of age or older; and you will use Sirturo in combination with pretomanid and linezolid
- You have an isolate of *Mycobacterium tuberculosis* that is resistant to isoniazid, rifampin, a fluoroquinolone, and an aminoglycoside antibiotic; you are 18 years of age or older; and you will use Sirturo in combination with pretomanid and linezolid

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEDAQUILINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sirturo or pretomanid.

REFERENCES

Sirturo [Prescribing Information]. Titusville, NJ: Janssen Therapeutics; July 2025.
Pretomanid [Prescribing Information]. Morgantown, WV: Mylan; November 2024.

Created: 05/13
Effective: 08/25/25 Client Approval: 08/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELANTAMAB MAFODOTIN-BLMF

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELANTAMAB MAFODOTIN-BLMF	BLENREP	46762		GPI-10 (2135051520)	

GUIDELINES FOR USE

Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Blenrep will be used in combination with bortezomib and dexamethasone
The patient has received at least two prior lines of therapy, including a proteasome inhibitor (e.g., Ninlaro [ixazomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide])

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELANTAMAB MAFODOTIN-BLMF (Blenrep)** requires the following rule(s) be met for approval:
You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
You are 18 years of age or older
Blenrep will be used in combination with bortezomib and dexamethasone
You have received at least two prior lines of therapy, including a proteasome inhibitor (such as Ninlaro [ixazomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Blenrep.

REFERENCES

Blenrep [Prescribing Information]. Durham, NC: GlaxoSmithKline; October 2025.

Created: 11/25
Effective: 12/01/25 Client Approval: 11/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELIMUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELIMUMAB	BENLYSTA	37462		GPI-10 (9942201500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
The patient is 5 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist
The patient is currently using corticosteroids, antimalarials, NSAIDs, or immunosuppressives
Benlysta will NOT be used concurrently with another systemic biologic (e.g., Saphnelo [anifrolumab-fnia]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE

If yes, **approve the requested strength for 6 months by GPID or GPI-14 as follows:**
200mg/mL (all formulations): #4mL per 28 days.
120mg, 400mg: no quantity limit.

If no, continue to #2.

Does the patient have a diagnosis of lupus nephritis (ICD-10 M32.14) and meet **ALL** of the following criteria?
The patient is 5 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist or nephrologist
The patient is receiving standard therapy (e.g., steroids, antimalarials, NSAIDs, immunosuppressives)
Benlysta will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of lupus nephritis

If yes, **approve the requested strength for a total of 6 months by GPID or GPI-14 as follows:**
120mg, 400mg: Approve for 6 months by GPID or GPI-14 with no quantity limit.
200mg/mL (all formulations):
<u>FIRST APPROVAL</u>: Approve for 1 month with a quantity limit of #8mL per 28 days.
<u>SECOND APPROVAL</u>: Approve for 5 months with a quantity limit of #4mL per 28 days (Please enter a start date 3 weeks after the start date of the first approval).

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BELIMUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELIMUMAB (Benlysta)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Systemic lupus erythematosus (SLE: a type of immune condition)
- Lupus nephritis (LN: a type of immune condition that affects the kidneys)

If you have systemic lupus erythematosus, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You are currently using corticosteroids, antimalarials, non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (standard therapy for the treatment of systemic lupus erythematosus [SLE])
- You will NOT use Benlysta concurrently (at the same time) with another systemic biologic (such as Sahnelo [anifrolumab-fnia]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of SLE

If you have lupus nephritis, approval also requires:
- You are 5 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)
- You are receiving standard treatment (such as steroids, antimalarials, nonsteroidal anti-inflammatory drugs [NSAIDs], or immunosuppressives
- You will NOT use Benlysta concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of lupus nephritis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BELIMUMAB

RENEWAL CRITERIA

Does the patient have a diagnosis of systemic lupus erythematosus (SLE) (ICD-10 Group M32) and meet **ALL** of the following criteria?
- The patient has shown clinical improvement while on Benlysta
- Benlysta will NOT be used concurrently with another systemic biologic (e.g., Saphnelo [anifrolumab-fnia]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SLE

If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
200mg/mL (all formulations): #4mL per 28 days.
120mg, 400mg: no quantity limit.

If no, continue to #2.

Does the patient have a diagnosis of lupus nephritis (ICD-10 M32.14) and meet **ALL** of the following criteria?
- The patient has shown clinical improvement in renal response as compared to baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid dose)
- Benlysta will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of lupus nephritis

If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
200mg/mL (all formulations): #4mL per 28 days.
120mg, 400mg: no quantity limit.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BELIMUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELIMUMAB (Benlysta)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Systemic lupus erythematosus (SLE: a type of immune condition)
- Lupus nephritis (LN: a type of immune condition that affects the kidneys)

If you have systemic lupus erythematosus, renewal also requires:
- You have shown clinical improvement while on Benlysta
- You will NOT use Benlysta concurrently (at the same time) with another systemic biologic (such as Sahnelo [anifrolumab-fnia]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic lupus erythematosus

If you have lupus nephritis, renewal also requires:
- You have shown clinical improvement in renal (kidney) response as compared to baseline (before starting Benlysta) laboratory values (estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] or proteinuria [level of protein in the urine]), and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid dose)
- You will NOT use Benlysta concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of lupus nephritis

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Benlysta.

REFERENCES

Benlysta [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline LLC; May 2024.

Created: 08/17
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 01/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELINOSTAT (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELINOSTAT	BELEODAQ	41264		GPI-10 (2153152000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL)
AND meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELINOSTAT (Beleodaq)** requires that the following rule be met for approval:
You have a diagnosis of relapsed or refractory (your condition has gotten worse after improving) peripheral T-cell lymphoma (PTCL; cancer that affects a type of immune system cells)
You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Beleodaq.

REFERENCES

Beleodaq [Prescribing Information]. Irvine, CA: Spectrum Pharmaceuticals; January 2020

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 07/14
Client Approval: 04/20
P&T Approval: 08/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELUMOSUDIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELUMOSUDIL MESYLATE	REZUROCK	47503		GPI-10 (9939851050)	

GUIDELINES FOR USE

Does the patient have a diagnosis of chronic graft-versus-host-disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- The patient has failed at least TWO lines of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to Jakafi (ruxolitinib)
- Rezurock will NOT be used concurrently with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BELUMOSUDIL (Rezurock)** requires the following rule(s) be met for approval:
- You have chronic graft-versus-host-disease (cGVHD: a type of long-term immune disorder)
- You are 12 years of age or older
- You have failed at least TWO lines of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil), one of which must be a trial of or contraindication to (harmful for you to use) Jakafi (ruxolitinib)
- You will NOT use Rezurock concurrently (at the same time) with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezurock.

REFERENCES

Rezurock [Prescribing Information]. Bridgewater, NJ: Kadmon Pharmaceuticals, LLC; December 2024.

Created: 08/21
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BELZUTIFAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELZUTIFAN	WELIREG	47546		GPI-10 (2142102000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of von Hippel-Lindau (VHL) disease (ICD-10 Q85.83) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient requires therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET)
- The patient does NOT require immediate surgery

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
If no, continue to #2.

Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Welireg will be used for adjuvant treatment
- Welireg will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph)
- The patient has renal cell carcinoma with a clear cell component (ccRCC)
- The patient is at intermediate-high or high risk of recurrence following a nephrectomy, or following a nephrectomy and resection of metastatic lesions

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
If no, continue to #3.

Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has renal cell carcinoma with a clear cell component (ccRCC)
- The patient was previously treated with a programmed death receptor-1 (PD-1) inhibitor (e.g., Keytruda [pembrolizumab]) OR a programmed death-ligand 1 (PD-L1) inhibitor (e.g., Bavencio [avelumab])
- The patient was previously treated with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) (e.g., Nexavar [sorafenib])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
If no, continue to #4.

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BELZUTIFAN

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of pheochromocytoma (ICD-10 Groups D35.0, C74.1) or paraganglioma (PPGL) (ICD-10 D44.7, C75.5) and meet **ALL** of the following criteria?
The patient is 12 years of age or older
The patient's tumor is locally advanced, unresectable, or metastatic

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
If no, do not approve.

DENIAL TEXT: Our guideline named **BELZUTIFAN (Welireg)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Von Hippel-Lindau (VHL) disease (a genetic disorder that causes tumors to grow in the body)
- Renal cell carcinoma (RCC: a type of kidney cancer)
- pheochromocytoma (a type of rare tumor) or paraganglioma (a type of nerve condition)

If you have von Hippel-Lindau disease, approval also requires:
- You are 18 years of age or older
- You require therapy for associated renal cell carcinoma (RCC: a type of kidney cancer), central nervous system (CNS) hemangioblastomas (tumor in the brain or spinal cord), or pancreatic neuroendocrine tumors (pNET: tumor in the pancreas)
- You do NOT require immediate surgery

If you have renal cell carcinoma, approval also requires ONE of the following:
- You are 18 years of age or older; AND Welireg will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph); AND Welireg will be used for adjuvant (add-on) treatment; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer); AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)
- You are 18 years of age or older; AND your cancer is advanced; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer); AND you were previously treated with a programmed death receptor-1 (PD-1) inhibitor (such as Keytruda [pembrolizumab]) OR a programmed death-ligand 1 (PD-L1) inhibitor (such as Bavencio [avelumab]); AND you were previously treated with a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) (such as Nexavar [sorafenib])

If you have pheochromocytoma or paraganglioma, approval also requires:
- You are 12 years of age or older
- Your tumor is locally advanced (spread from where it started to nearby tissue or lymph nodes), unresectable (cannot be removed by surgery), or metastatic (has spread to other parts of the body)

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BELZUTIFAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Welireg.

REFERENCES

Welireg [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; June 2026.

Created: 10/21
Effective: 07/01/26 Client Approval: 06/26 DMC Approval: 07/26

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STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BENRALIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BENRALIZUMAB	FASENRA	44635		GPI-10 (4460402000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
- The patient has a blood eosinophil level of at least 150 cells/mcL within the past 12 months
- Fasenra will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
- Fasenra will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

If yes, continue to #2.
If no, continue to #4.

Does the patient meet **ONE** of the following criteria?
- The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
- The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

If yes, **approve all strengths and formulations for a total of 4 months by GPID or GPI-14. Please enter two authorizations as follows:**
FIRST APPROVAL: Approve for 2 months with the following quantity limits:
10mg/0.5mL: #0.5mL per 28 days.
30mg/mL: #1mL per 28 days.
SECOND APPROVAL: Approve for 2 months with the following quantity limits (please enter a start date of 1 week before the end date of the first approval):
10mg/0.5mL: #0.5mL per 56 days.
30mg/mL: #1mL per 56 days.

If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
- Daytime asthma symptoms more than twice per week
- Any night waking due to asthma
- Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
- Any activity limitation due to asthma

If yes, **approve all strengths and formulations for a total of 4 months by GPID or GPI-14. Please enter two authorizations as follows:**
FIRST APPROVAL: Approve for 2 months with the following quantity limits:
10mg/0.5mL: #0.5mL per 28 days.
30mg/mL: #1mL per 28 days.
SECOND APPROVAL: Approve for 2 months with the following quantity limits (please enter a start date of 1 week before the end date of the first approval):
10mg/0.5mL: #0.5mL per 56 days.
30mg/mL: #1mL per 56 days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Fasenra will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

If yes, **approve all formulations of the 30mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

If no, continue to #5.

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- The patient has HES without an identifiable non-hematologic secondary cause
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- The patient has a blood eosinophil count of at least 1000 cell/mcL at initiation of therapy
- The patient has a negative FIP1L1-PDGFRA test
- The patient has been stable on HES therapy (corticosteroid [e.g., prednisone]) for at least 4 weeks
- Fasenra will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HES

If yes, **approve all formulations of the 30mg strength for 6 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
- Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
- Hypereosinophilic syndrome (HES: a type of blood disorder)

(Initial denial text continued on next page)

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have severe asthma with an eosinophilic phenotype, approval also requires:
- You are 6 years of age or older
- Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
- You have a blood eosinophil level (a type of lab test) of at least 150 cells/mcL within the past 12 months
- Fasenra will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as formoterol, salmeterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline, or an oral corticosteroid [such as prednisone])
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of lung condition with inflammation)
- You meet ONE of the following:
  - You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
  - You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
  - You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
    - Daytime asthma symptoms more than twice per week
    - Any night waking due to asthma
    - Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
    - Any activity limitation due to asthma

If you have eosinophilic granulomatosis with polyangiitis, approval also requires:
- You are 18 years of age or older
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis (a type of immune system disorder with inflammation of blood vessels)

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

If you have hypereosinophilic syndrome, approval also requires:

- You are 12 years of age or older
- You have hypereosinophilic syndrome (HES: a type of blood disorder) without an identifiable non-hematologic (not present in the blood) secondary cause (HES is not caused by another condition)
- Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
- You have a blood eosinophil count (a type of lab test) of at least 1000 cells/mcL at the start of therapy
- You have a negative FIP1L1-PDFRA test (a type of lab test that detects a type of gene mutation)
- You have been stable on hypereosinophilic syndrome (HES: a type of blood disorder) therapy (corticosteroid [such as prednisone]) for at least 4 weeks
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome (a type of blood disorder)

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BENRALIZUMAB

RENEWAL CRITERIA

Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
- The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
- Fasenra will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

If yes, continue to #2.
If no, continue to #3.

Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
- Reduction in asthma exacerbations from baseline
- Decreased utilization of rescue medications (e.g., albuterol)
- Increase in percent predicted FEV1 from pre-treatment baseline
- Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

If yes, **approve all strengths and formulations for 12 months by GPID or GPI-14 with the following quantity limits:**
10mg/0.5mL: #0.5mL per 56 days.
30mg/mL: #1mL per 56 days.

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
- The patient has a reduction in EGPA symptoms compared to baseline OR has been able to reduce/eliminate corticosteroid (e.g., prednisone) use
- Fasenra will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

If yes, **approve all formulations of the 30mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

If no, continue to #4.

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BENRALIZUMAB

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and meet **ALL** of the following criteria?
- The patient has a reduction in frequency/severity of HES flares
- The patient has improved symptoms or reduced oral steroid (e.g., prednisone) requirements
- Fasenra will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HES

If yes, **approve all formulations of the 30mg strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
- Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
- Hypereosinophilic syndrome (HES: a type of blood disorder)

If you have severe asthma with an eosinophilic phenotype, renewal also requires:
- You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of lung condition with inflammation)

(Renewal denial text continued on next page)

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BENRALIZUMAB

RENEWAL CRITERIA (CONTINUED)

You have shown a clinical response as evidenced by ONE of the following:
- You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Fasenra)
- You have decreased your use of rescue medications (such as albuterol)
- Your percent predicted FEV1 (a type of lung test) has increased from pre-treatment baseline (before starting Fasenra)
- You have experienced a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

If you have eosinophilic granulomatosis with polyangiitis, renewal also requires:
- You have a reduction in eosinophilic granulomatosis with polyangiitis (a type of immune system disorder with inflammation of blood vessels) symptoms compared to baseline (before starting Fasenra), OR you have been able to decrease or eliminate (stop) corticosteroid (such as prednisone) use
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of EGPA (a type of immune system disorder with inflammation of blood vessels)

If you have hypereosinophilic syndrome, renewal also requires:
- You have a reduction in frequency/severity of hypereosinophilic syndrome (HES: a type of blood disorder) flares
- You have improved symptoms or reduced oral steroid (such as prednisone) requirements
- You will NOT use Fasenra concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome (a type of blood disorder)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fasenra.

REFERENCES

Fasenra [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BERDAZIMER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BERDAZIMER SODIUM	ZELSUVMI	49364		GPI-10 (9035001450)	

GUIDELINES FOR USE

Does the patient have a diagnosis of molluscum contagiosum (MC) (ICD-10 B08.1) and meet **ALL** of the following criteria?
The patient is 1 year of age or older
Zelsuvmi will NOT be used concurrently with another topical agent for the treatment of molluscum contagiosum (e.g., Ycanth [cantharidin], Condylox [podofilox])
The patient had a trial of or contraindication to the clinical standard of care agent: podofilox 0.5% topical solution

If yes, **approve for 12 weeks by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BERDAZIMER (Zelsuvmi)** requires the following rule(s) be met for approval:
You have molluscum contagiosum (MC: a viral skin infection)
You are 1 year of age or older
You will NOT use Zelsuvmi concurrently (at the same time) with another topical medication for the treatment of molluscum contagiosum (a viral skin infection) (such as Ycanth [cantharidin], Condylox [podofilox])
You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: podofilox 0.5% topical solution

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zelsuvmi.

REFERENCES

Zelsuvmi [Prescribing Information]. Wilmington, DE: EPIH SPV, LLC.; January 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEROTRALSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEROTRALSTAT HYDROCHLORIDE	ORLADEYO	47016		GPI-10 (8584001020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Orladeyo will be used for prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Orladeyo will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, continue to #3.

Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
- The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
- Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEROTRALSTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for approval:

- You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- You are 2 years of age or older
- Orladeyo will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
- Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
- You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii], Dawnzera [donidalorsen])
- You meet ONE of the following:
  - You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
  - You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
    - You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
    - Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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BEROTRALSTAT

RENEWAL CRITERIA

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient has experienced an improvement in HAE attacks (reductions in attack frequency or attack severity) compared to baseline
- Orladeyo will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for renewal:
- You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- You have experienced an improvement in hereditary angioedema (a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
- You will NOT use Orladeyo concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orladeyo.

REFERENCES

Orladeyo [Prescribing Information]. Durham, NC: BioCryst Pharmaceuticals, Inc.; December 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BETAINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BETAINE	CYSTADANE, BETAINE ANHYDROUS	12233		GPI-10 (3090452000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of homocystinuria (ICD-10 E72.11) (including cystathionine beta-synthase [CBS] deficiency [ICD-10 E72.11], 5,10-methylenetetrahydrofolate reductase [MTHFR] deficiency [ICD-10 E72.12], cobalamin cofactor metabolism [cbl] defect)?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #20 grams per day.** If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BETAINE (Cystadane)** requires the following rule(s) be met for approval:
You have homocystinuria (a type of genetic metabolic disorder), including cystathionine beta-synthase (CBS: a type of enzyme) deficiency, 5,10-methylenetetrahydrofolate reductase (MTHFR: a type of enzyme) deficiency, cobalamin cofactor metabolism (cbl: vitamin B12 that is required for enzyme activity) defect

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystadane.

REFERENCES

Cystadane [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; October 2019.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB	AVASTIN, BEVACIZUMAB	25963		GPI-10 (2133502000, 8665502000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) **AND** meet the following criterion?
- The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

  If yes, continue to #2.
  If no, continue to #6.

Does the patient meet **ONE** of the following criteria?
- Avastin will be used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment
- Avastin will be used in combination with fluoropyrimidine- irinotecan- (i.e., FOLFIRI) OR fluoropyrimidine-oxaliplatin- (i.e., FOLFOX, CapeOx) based chemotherapy as a second-line treatment AND the patient has progressed on a first-line bevacizumab product containing regimen

  If yes, **approve for 12 months by HICL or GPI-10.**
  If no, continue to #3.

Does the patient meet **ALL** of the following criteria?
- Avastin will be used in combination with Lonsurf (trifluridine and tipiracil)
- The patient previously received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF biological therapy [e.g., Zaltrap (ziv-aflibercept), Cyramza (ramucirumab)]

  If yes, continue to #4.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's metastatic colorectal cancer RAS wild-type?

  If yes, continue to #5.
  If no, **approve for 12 months by HICL or GPI-10.**

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BEVACIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

Has the patient had treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
Avastin will be used in combination with carboplatin and paclitaxel for first-line treatment
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #8.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) and meet **ALL** of the following criteria?
Avastin will be used in combination with interferon alfa
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #9.

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BEVACIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

Will Avastin be used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
- The patient is not concurrently using other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, continue to #10.

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer and meet **ALL** of the following criteria?
- Avastin will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #11.

Does the patient have a diagnosis of platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ALL** of the following criteria?
- Avastin will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
- The patient has received no more than 2 prior chemotherapy regimens
- The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #12.

Does the patient have a diagnosis of platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ONE** of the following criteria?
- Avastin will be used in combination with carboplatin and paclitaxel
- Avastin will be used in combination with carboplatin and gemcitabine
- Avastin will be used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, continue to #13.
If no continue to #14.

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BEVACIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

Has the patient had a trial of or contraindication to **ONE** of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
Avastin will be used following initial surgical resection
Avastin will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #15.

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) and meet **ALL** of the following criteria?
Avastin will be used in combination with Tecentriq (atezolizumab)
The patient has not received prior systemic therapy
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEVACIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB (Avastin)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain tumor)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
- An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
- Platinum-resistant recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Platinum-sensitive recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Stage III or IV epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

If you have metastatic colorectal cancer, approval also requires:
You meet ONE of the following:
- Avastin will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
- Your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen AND Avastin will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy as a second-line treatment
- Avastin will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])

You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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BEVACIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Avastin will be used in combination with carboplatin and paclitaxel for first-line treatment
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have metastatic renal cell carcinoma, approval also requires:
- Avastin will be used in combination with interferon-alfa
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
- You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If you have persistent, recurrent, or metastatic cervical cancer, **approval also requires:**
- Avastin will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
- Avastin will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
- You have received no more than two prior chemotherapy regimens
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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BEVACIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
- You meet ONE of the following:
  - Avastin will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine
  - Avastin will be used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
- Avastin will be used following initial surgical resection (removal)
- Avastin will be used in combination with carboplatin and paclitaxel OR as a single agent after previous use in combination with carboplatin and paclitaxel
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
- Avastin will be used in combination with Tecentriq (atezolizumab)
- You have not received prior systemic therapy (treatment that spreads throughout the body)
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB (NSA)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Is Avastin being used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
The patient is not concurrently using other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB (Avastin)** requires the following rule(s) be met for renewal:
You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Avastin.

REFERENCES

Avastin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2022.
Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; August 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 09/18/23
Created: 02/13
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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIUMAB-ADCD (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB-ADCD	VEGZELMA	48357		GPI-10 (2133502010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC)?

If yes, continue to #2.
If no, continue to #6.

Does the patient meet **ONE** of the following criteria?
- Vegzelma will be used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment
- Vegzelma will be used in combination with fluoropyrimidine-irinotecan- (i.e., FOLFIRI) or fluoropyrimidine-oxaliplatin- (i.e., FOLFOX, CapeOx) based chemotherapy as a second-line treatment AND the patient has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Does the patient meet **ALL** of the following criteria?
- Vegzelma will be used in combination with Lonsurf (trifluridine and tipiracil)
- The patient previously received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF biological therapy [e.g., Zaltrap (ziv-aflibercept), Cyramza (ramucirumab)]

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's metastatic colorectal cancer RAS wild-type?

If yes, continue to #5.
If no, **approve for 12 months by HICL or GPI-10.**

Has the patient had treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEVACIZUMAB-ADCD (NSA)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
Vegzelma will be used in combination with carboplatin and paclitaxel for first-line treatment

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #8.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) **AND** meet the following criterion?
Vegzelma will be used in combination with interferon alfa

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #9.

Will Vegzelma be used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
The patient is not concurrently using other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, continue to #10.

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer and meet **ONE** of the following criteria?
Vegzelma will be used in combination with paclitaxel and cisplatin
Vegzelma will be used in combination with paclitaxel and topotecan

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #11.

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BEVACIZUMAB-ADCD (NSA)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
Vegzelma will be used following initial surgical resection
Vegzelma will be used in combination with carboplatin and paclitaxel OR as a single agent after prior use in combination with carboplatin and paclitaxel

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #12.

Does the patient have a diagnosis of platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ALL** of the following criteria?
Vegzelma will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
The patient has received no more than two prior chemotherapy regimens

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #13.

Does the patient have a diagnosis of platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ONE** of the following criteria?
Vegzelma will be used in combination with carboplatin and paclitaxel
Vegzelma will be used in combination with carboplatin and gemcitabine
Vegzelma will be used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #14.

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) and meet **ALL** of the following criteria?
Vegzelma will be used in combination with Tecentriq (atezolizumab)
The patient has not received prior systemic therapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEVACIZUMAB-ADCD (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-ADCD (Vegzelma)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain tumor)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
- An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
- Stage III or IV epithelial ovarian, fallopian tube (female sex organs), or primary peritoneal (abdomen) cancer
- Platinum-resistant recurrent epithelial ovarian, fallopian tube (female sex organs), or primary peritoneal (abdomen) cancer
- Platinum-sensitive recurrent epithelial ovarian, fallopian tube (female sex organs), or primary peritoneal (abdomen) cancer
- Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

If you have metastatic colorectal cancer, approval also requires ONE of the following:
- Vegzelma will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
- Your disease has progressed (gotten worse) on a first-line bevacizumab-containing regimen AND Vegzelma will be used in combination with fluoropyrimidine- irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy as a second-line treatment
- Vegzelma will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Vegzelma will be used in combination with carboplatin and paclitaxel for first-line treatment

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BEVACIZUMAB-ADCD (NSA)

INITIAL CRITERIA (CONTINUED)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older

If you have metastatic renal cell carcinoma, approval also requires:
- Vegzelma will be used in combination with interferon-alfa

If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
- You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VGEF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:
- Vegzelma will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

If you have Stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
- Vegzelma will be used following initial surgical resection (removal)
- Vegzelma will be used in combination with carboplatin and paclitaxel OR as a single agent after previous use in combination with carboplatin and paclitaxel

If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
- Vegzelma will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
- You have received no more than two prior chemotherapy regimens

If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires ONE of the following:
- Vegzelma will be used in combination with carboplatin and paclitaxel OR with carboplatin and gemcitabine
- Vegzelma will be used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
- Vegzelma will be used in combination with Tecentriq (atezolizumab)
- You have not received prior systemic therapy (treatment that spreads throughout the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB-ADCD (NSA)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Is Vegzelma being used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
The patient is not concurrently using other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-ADCD (Vegzelma)** requires the following rule(s) be met for renewal:
You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB-ADCD (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vegzelma, Avastin, and Lonsurf.

REFERENCES

Vegzelma [Prescribing Information]. Incheon, Republic of Korea: Celltrion, Inc.; February 2023.
Avastin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2022.
Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; August 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 09/18/23
Created: 02/23
Client Approval: 09/23
P&T Approval: 10/23

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-AWWB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB-AWWB	MVASI	44500		GPI-10 (2133502020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC)?

If yes, continue to #2.
If no, continue to #6.

Does the patient meet **ONE** of the following criteria?
Mvasi will be used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment
Mvasi will be used in combination with fluoropyrimidine-irinotecan (i.e., FOLFIRI) or fluoropyrimidine-oxaliplatin (i.e., FOLFOX, CapeOx) based chemotherapy as a second-line treatment AND the patient has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue #3.

Does the patient meet **ALL** of the following criteria?
Mvasi will be used in combination with Lonsurf (trifluridine and tipiracil)
The patient previously received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF biological therapy [e.g., Zaltrap (ziv-aflibercept), Cyramza (ramucirumab)]

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's metastatic colorectal cancer RAS wild-type?

If yes, continue to #5.
If no, **approve for 12 months by HICL or GPI-10.**

Has the patient had treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEVACIZUMAB-AWWB (NSA)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
Mvasi will be used in combination with carboplatin and paclitaxel for first-line treatment

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #8.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) **AND** meet the following criterion?
Mvasi will be used in combination with interferon-alfa

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #9.

Will Mvasi be used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
The patient is not concurrently using other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, continue to #10.

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer and meet **ONE** of the following criteria?
Mvasi will be used in combination with paclitaxel and cisplatin
Mvasi will be used in combination with paclitaxel and topotecan

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #11.

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BEVACIZUMAB-AWWB (NSA)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
Mvasi will be used following initial surgical resection
Mvasi will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

If yes, **approve 12 months by HICL or GPI-10.**
If no, continue to #12.

Does the patient have a diagnosis of platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
Mvasi will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
The patient has received no more than two prior chemotherapy regimens

If yes, **approve 12 months by HICL or GPI-10.**
If no, continue to #13.

Does the patient have a diagnosis of platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ONE** of the following criteria?
Mvasi will be used in combination with carboplatin and paclitaxel
Mvasi will be used in combination with carboplatin and gemcitabine
Mvasi will be used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, **approve 12 months by HICL or GPI-10.**
If no, continue to #14.

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) and meet **ALL** of the following criteria?
Mvasi will be used in combination with Tecentriq (atezolizumab)
The patient has not received prior systemic therapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEVACIZUMAB-AWWB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-AWWB (Mvasi)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain tumor)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
- An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
- Stage III or IV epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Platinum-resistant recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Platinum-sensitive recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

If you have metastatic colorectal cancer, approval also requires ONE of the following:
- Mvasi will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
- Your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen AND Mvasi will be used in combination with fluoropyrimidine-irinotecan (such as FOLFIRI) or fluoropyrimidine-oxaliplatin (such as FOLFOX, CAPeOX) based chemotherapy as a second-line treatment
- Mvasi will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Mvasi will be used in combination with carboplatin and paclitaxel for first-line treatment

(Initial denial text continued on the next page)

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BEVACIZUMAB-AWWB (NSA)

INITIAL CRITERIA (CONTINUED)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older

If you have metastatic renal cell carcinoma, approval also requires:
- Mvasi will be used in combination with interferon-alfa

If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
- You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If you have persistent, recurrent, or metastatic cervical cancer, **approval also requires:**
- Mvasi will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

If you have Stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
- Mvasi will be used following initial surgical resection (removal)
- Mvasi will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

If you have platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
- Mvasi will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
- You have received no more than two prior chemotherapy regimens

If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires ONE of the following:
- Mvasi will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine
- Mvasi will be used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
- Mvasi will be used in combination with Tecentriq (atezolizumab)
- You have not received prior systemic therapy (treatment that spreads throughout the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB-AWWB (NSA)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Is Mvasi being used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
The patient is not concurrently using other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-AWWB (Mvasi)** requires the following rule(s) be met for renewal:
You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB-AWWB (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mvasi and Avastin.

REFERENCES

Mvasi [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; February 2023.
Avastin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2022.
Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; August 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 09/18/23
Created: 07/19
Client Approval: 09/23
P&T Approval: 10/23

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-BVZR (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB-BVZR	ZIRABEV	45849		GPI-10 2133502030	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC)?

If yes, continue to #2.
If no, continue to #6.

Does the patient meet **ONE** of the following criteria?
- Zirabev will be used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment
- Zirabev will be used in combination with fluoropyrimidine- irinotecan- (i.e., FOLFIRI) or fluoropyrimidine-oxaliplatin- (i.e., FOLFOX, CapeOx) based chemotherapy as a second-line treatment AND the patient has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Does the patient meet **ALL** of the following criteria?
- Zirabev will be used in combination with Lonsurf (trifluridine and tipiracil)
- The patient previously received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF biological therapy [e.g., Zaltrap (ziv-aflibercept), Cyramza (ramucirumab)]

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's metastatic colorectal cancer RAS wild-type?

If yes, continue to #5.
If no, **approve for 12 months by HICL or GPI-10.**

Has the patient had treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEVACIZUMAB-BVZR (NSA)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
Zirabev will be used in combination with carboplatin and paclitaxel for first-line treatment

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #8.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) **AND** meet the following criterion?
Zirabev will be used in combination with interferon-alfa

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #9.

Will Zirabev be used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
The patient is not concurrently using other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, continue to #10.

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer and meet **ONE** of the following criteria?
Zirabev will be used in combination with paclitaxel and cisplatin
Zirabev will be used in combination with paclitaxel and topotecan

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #11.

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BEVACIZUMAB-BVZR (NSA)

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
Zirabev will be used following initial surgical resection
Zirabev will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #12.

Does the patient have a diagnosis of platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ALL** of the following criteria?
Zirabev will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
The patient has received no more than two prior chemotherapy regimens

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #13.

Does the patient have a diagnosis of platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ONE** of the following criteria?
Zirabev will be used in combination with carboplatin and paclitaxel
Zirabev will be used in combination with carboplatin and gemcitabine
Zirabev will be used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above
If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #14.

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) and meet **ALL** of the following criteria?
Zirabev will be used in combination with Tecentriq (atezolizumab)
The patient has not received prior systemic therapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEVACIZUMAB-BVZR (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-BVZR (Zirabev)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain tumor)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
- An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
- Stage III or IV epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Platinum-resistant recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Platinum-sensitive recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

If you have metastatic colorectal cancer, approval also requires ONE of the following:
- Zirabev will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
- Your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen AND Zirabev will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CAPeOX) based chemotherapy as a second-line treatment
- Zirabev will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Zirabev will be used in combination with carboplatin and paclitaxel for first-line treatment

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BEVACIZUMAB-BVZR (NSA)

INITIAL CRITERIA (CONTINUED)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older

If you have metastatic renal cell carcinoma, approval also requires:
- Zirabev will be used in combination with interferon-alfa

If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
- You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:
- Zirabev will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

If you have Stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
- Zirabev will be used following initial surgical resection (removal)
- Zirabev will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
- Zirabev will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
- You have received no more than two prior chemotherapy regimens

If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires ONE of the following:
- Zirabev will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine
- Zirabev will be used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
- Zirabev will be used in combination with Tecentriq (atezolizumab)
- You have not received prior systemic therapy (treatment that spreads throughout the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB-BVZR (NSA)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Is Zirabev being used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
The patient is not concurrently using other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-BVZR (Zirabev)** requires the following rule(s) be met for renewal:
You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB-BVZR (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zirabev and Avastin.

REFERENCES

Zirabev [Prescribing Information]. New York, New York: Pfizer Inc.; February 2023.
Avastin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2022.
Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; August 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 09/18/23
Created: 01/20
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P&T Approval: 10/23

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIUMAB-MALY (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB-MALY	ALYMSYS	47950		GPI-10 (2133502050)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) **AND** meet the following criterion?
- The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

  If yes, continue to #2.
  If no, continue to #6.

Does the patient meet **ONE** of the following criteria?
- Alymsys will be used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment
- Alymsys will be used in combination with fluoropyrimidine-irinotecan- (i.e., FOLFIRI) OR fluoropyrimidine-oxaliplatin- (i.e., FOLFOX, CapeOx) based chemotherapy as a second-line treatment AND the patient has progressed on a first-line bevacizumab product-containing regimen

  If yes, **approve for 12 months by HICL or GPI-10.**
  If no, continue to #3.

Does the patient meet **ALL** of the following criteria?
- Alymsys will be used in combination with Lonsurf (trifluridine and tipiracil)
- The patient previously received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF biological therapy [e.g., Zaltrap (ziv-aflibercept), Cyramza (ramucirumab)]

  If yes, continue to #4.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's metastatic colorectal cancer RAS wild-type?

  If yes, continue to #5.
  If no, **approve for 12 months by HICL or GPI-10.**

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BEVACIZUMAB-MALY (NSA)

INITIAL CRITERIA (CONTINUED)

Has the patient had treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
Alymsys will be used in combination with carboplatin and paclitaxel for first-line treatment
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #8.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) and meet **ALL** of the following criteria?
Alymsys will be used in combination with interferon alfa
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #9.

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BEVACIZUMAB-MALY (NSA)

INITIAL CRITERIA (CONTINUED)

Will Alymsys be used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
The patient is not concurrently using other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, continue to #10.

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer and meet **ALL** of the following criteria?
Alymsys will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #11.

Does the patient have a diagnosis of platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ALL** of the following criteria?
Alymsys will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
The patient has received no more than two prior chemotherapy regimens
The patient had a trial of or contraindication to ONE of the following preferred agents Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #12.

Does the patient have a diagnosis of platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ONE** of the following criteria?
Alymsys will be used in combination with carboplatin and paclitaxel
Alymsys will be used in combination with carboplatin and gemcitabine
Alymsys will be used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, continue to #13.
If no continue to #14.

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BEVACIZUMAB-MALY (NSA)

INITIAL CRITERIA (CONTINUED)

Has the patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
Alymsys will be used following initial surgical resection
Alymsys will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #15.

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) and meet **ALL** of the following criteria?
Alymsys will be used in combination with Tecentriq (atezolizumab)
The patient has not received prior systemic therapy
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEVACIZUMAB-MALY (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-MALY (Alymsys)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
- Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
- Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
- Recurrent glioblastoma (GBM: type of brain tumor)
- Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
- An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
- Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
- Platinum-resistant recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Platinum-sensitive recurrent epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Stage III or IV epithelial ovarian, fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
- Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

If you have metastatic colorectal cancer, approval also requires:
You meet ONE of the following:
- Alymsys will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
- Your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen AND Alymsys will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy as a second-line treatment
- Alymsys will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])

You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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BEVACIZUMAB-MALY (NSA)

INITIAL CRITERIA (CONTINUED)

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Alymsys will be used in combination with carboplatin and paclitaxel for first-line treatment
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have metastatic renal cell carcinoma, approval also requires:
- Alymsys will be used in combination with interferon-alfa
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
- You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:
- Alymsys will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
- Alymsys will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
- You have received no more than two prior chemotherapy regimens
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

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BEVACIZUMAB-MALY (NSA)

INITIAL CRITERIA (CONTINUED)

If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
- You meet ONE of the following:
  - Alymsys will be used in combination with carboplatin and paclitaxel OR with carboplatin and gemcitabine
  - Alymsys will be used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have stage III or IV epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:
- Alymsys will be used following initial surgical resection (removal)
- Alymsys will be used in combination with carboplatin and paclitaxel OR as a single agent after previous use in combination with carboplatin and paclitaxel
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
- Alymsys will be used in combination with Tecentriq (atezolizumab)
- You have not received prior systemic therapy (treatment that spreads throughout the body)
- You have tried or have a contraindication (harmful for) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB-MALY (NSA)

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Is Alymsys being used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
The patient has maintenance or improvement of visual acuity
The patient is not concurrently using other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-MALY (Alymsys)** requires the following rule(s) be met for renewal:
You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
You have maintenance or improvement of visual acuity (vision clarity or sharpness)
You are NOT concurrently (at the same time) using other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB-MALY (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alymsys and Avastin.

REFERENCES

Alymsys [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2022.
Avastin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2022.
Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; August 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 09/18/23
Created: 06/22
Client Approval: 09/23
P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-NWGD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB-NWGD	JOBEVNE	50512		GPI-10 (2133502055)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) **AND** meet the following criterion?
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, continue to #2.
If no, continue to #6.

Does the patient meet **ONE** of the following criteria?
Jobevne will be used in combination with intravenous 5-fluorouracil based chemotherapy
Jobevne will be used in combination with fluoropyrimidine- irinotecan- (e.g., FOLFIRI) or fluoropyrimidine-oxaliplatin- (e.g., FOLFOX, CapeOx) based chemotherapy AND the patient has progressed on a first-line bevacizumab product containing regimen

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Does the patient meet **ALL** of the following criteria?
Jobevne will be used in combination with Lonsurf (trifluridine and tipiracil)
The patient previously received treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF biological therapy [e.g., Zaltrap (ziv-aflibercept), Cyramza (ramucirumab)]

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's metastatic colorectal cancer RAS wild-type?

If yes, continue to #5.
If no, **approve for 12 months by HICL or GPI-10.**

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BEVACIZUMAB-NWGD

INITIAL CRITERIA (CONTINUED)

Has the patient had treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
Jobevne will be used in combination with carboplatin and paclitaxel
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

Does the patient have a diagnosis of recurrent glioblastoma (GBM) (ICD-10 (ICD-10 C72.9; Group C71) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #8.

Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
Jobevne will be used in combination with interferon alfa
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #9.

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BEVACIZUMAB-NWGD

INITIAL CRITERIA (CONTINUED)

Will Jobevne be used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
- Jobevne will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.**
If no, continue to #10.

Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer (ICD-10 Group C53) and meet **ALL** of the following criteria?
- Jobevne will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #11.

Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) **AND** meet the following criterion?
- The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, continue to #12.
If no, continue to 15.

Is the cancer platinum-resistant recurrent and the patient meets **ALL** of the following criteria?
- Jobevne will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
- The patient has received no more than 2 prior chemotherapy regimens

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #13.

Is the cancer platinum-sensitive recurrent and the patient meets **ONE** of the following criteria?
- Jobevne will be used in combination with carboplatin and paclitaxel
- Jobevne will be used in combination with carboplatin and gemcitabine
- Jobevne will be used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, **approve for 12 months by HICL or GPI-10**.
If no continue to #14.

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INITIAL CRITERIA (CONTINUED)

Is the cancer stage III or IV and the patient meets **ALL** of the following criteria?
Jobevne will be used following initial surgical resection
Jobevne will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #15.

Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
Jobevne will be used in combination with Tecentriq (atezolizumab)
The patient has not received prior systemic therapy
The patient had a trial of or contraindication to ONE of the following preferred agents: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd), Zirabev (bevacizumab-bvzr)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-NWGD (Jobevne)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
Recurrent glioblastoma (GBM: type of brain tumor)
Metastatic renal cell carcinoma (mRCC: type of kidney cancer that has spread in the body)
An ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendation
Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
Epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system or abdomen cancers)
Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)
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INITIAL CRITERIA (CONTINUED)

If you have metastatic colorectal cancer, approval also requires:
- You meet ONE of the following:
  - Jobevne will be used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy
  - Your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen AND Jobevne will be used in combination with fluoropyrimidine-irinotecan- (such as FOLFIRI) or fluoropyrimidine-oxaliplatin- (such as FOLFOX, CapeOx) based chemotherapy
  - Jobevne will be used in combination with Lonsurf (trifluridine and tipiracil), AND you have previously been treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) and an anti-VEGF biological therapy (such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab]). In addition, if you are RAS wild-type (a type of gene), you were previously treated with an anti-EGFR therapy (such as Erbitux [cetuximab], Vectibix [panitumumab])
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab- adcd), Zirabev (bevacizumab-bvzr)

If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:
- Jobevne will be used in combination with carboplatin and paclitaxel
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab- adcd), Zirabev (bevacizumab-bvzr)

If you have recurrent glioblastoma, approval also requires:
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) to ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab- adcd), Zirabev (bevacizumab-bvzr)

If you have metastatic renal cell carcinoma, approval also requires:
- Jobevne will be used in combination with interferon-alfa
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab- adcd), Zirabev (bevacizumab-bvzr)

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INITIAL CRITERIA (CONTINUED)

If you have any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor) or retina (a part of the eye) specialist
- You will NOT Jobevne concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic (eye) indication

If you have persistent, recurrent, or metastatic cervical cancer, **approval also requires:**
- Jobevne will be used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab- adcd), Zirabev (bevacizumab-bvzr)

If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
- You meet ONE of the following:
  - Your cancer is platinum-resistant recurrent (no longer responds to a type of treatment); Jobevne will be used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan; AND you have received no more than 2 prior chemotherapy regimens (received no more than 2 prior chemotherapy regimens)
  - Your cancer is platinum-sensitive recurrent (responds to a type of treatment); AND Jobevne will be used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine, OR as a single agent after previous use in combination with one of these carboplatin-containing chemotherapy regimens
  - Your cancer is stage III or IV; Jobevne will be used following initial surgical resection (removal); AND Jobevne will be used in combination with carboplatin and paclitaxel, or as a single agent after previous use in combination with carboplatin and paclitaxel
- You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab- adcd), Zirabev (bevacizumab-bvzr)

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INITIAL CRITERIA (CONTINUED)

If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:

Jobevne will be used in combination with Tecentriq (atezolizumab)

You have not received prior systemic therapy (treatment that spreads throughout the body)

You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab- adcd), Zirabev (bevacizumab-bvzr)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEVACIZUMAB-NWGD

RENEWAL CRITERIA

NOTE: For diagnoses other than an ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation, please refer to the initial criteria section.

Is Jobevne being used to treat any ophthalmic indication listed in Micromedex/Drugdex with Class I, IIa, or IIb recommendation and the patient meets **ALL** of the following criteria?
- The patient has maintenance or improvement of visual acuity
- Jobevne will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 30 days.** If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-NWGD (Jobevne)** requires the following rule(s) be met for renewal:
- You have an ophthalmic (eye) indication listed in Micromedex/Drugdex (drug database) with Class I, IIa, or IIb recommendations
- You have maintenance or improvement of visual acuity (vision clarity or sharpness)
- You will NOT Jobevne concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Susvimo [ranibizumab], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for any ophthalmic indication

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jobevne, Avastin, and Lonsurf.

REFERENCES

Jobevne [Prescribing Information]. Cambridge, MA: Biosimilars Newco, Ltd.; April 2025.
Avastin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2022.
Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; August 2023.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEXAROTENE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEXAROTENE	TARGRETIN, BEXAROTENE	20832		GPI-10 (2170822000, 9037622000)	

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

TARGRETIN (BEXAROTENE) CAPSULE

Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL) (ICD-10 Group C84.A)
AND meet the following criterion?
The patient is refractory to at least one prior systemic therapy (e.g., gemcitabine, methotrexate, liposomal doxorubicin, bortezomib)

If yes, **approve for 12 months by GPID or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEXAROTENE (Targretin capsule)** requires the following rule(s) be met for approval:
You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer)
You are refractory (condition does not respond to treatment) to at least one prior systemic therapy (treatment that targets the entire body, such as gemcitabine, methotrexate, liposomal doxorubicin, bortezomib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BEXAROTENE

GUIDELINES FOR USE (CONTINUED)

TARGRETIN (BEXAROTENE) GEL

Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL) (Stage IA or IB) (ICD-10 Group C84.A) and meet **ONE** of the following criteria?
The patient has refractory or persistent disease after other therapies
The patient has not tolerated other therapies

If yes, **approve for 12 months by GPID or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEXAROTENE (Targretin gel)** requires the following rule(s) to be met for approval:
You have cutaneous T-cell lymphoma (CTCL: a type of blood cancer) (Stage IA or IB)
You meet ONE of the following:
- You have refractory (condition does not respond) or persistent (condition continues to exist) disease after other therapies
- You have not tolerated other therapies

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Targretin.

REFERENCES

Targretin Capsule [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; April 2020.
Targretin Gel [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; February 2020.

Created: 05/12
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BIMEKIZUMAB-BKZX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BIMEKIZUMAB-BKZX	BIMZELX	47629		GPI-10 (9025051800)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient is a candidate for systemic therapy or phototherapy
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, continue to #2.
If no, continue to #4.

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient was previously stable on another biologic and is switching to Bimzelx
- The patient has psoriasis covering 3 percent or more of body surface area (BSA)
- The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, continue to #5.
If no, continue to #6.

Does the patient have coexistent moderate to severe plaque psoriasis (PsO)? (**Note:** For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.**

Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
- The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)

If yes, continue to #7.
If no, continue to #8.

Does the patient meet **ONE** of the following criteria?
- The patient was previously stable on another biologic and is switching to Bimzelx
- The patient has C-reactive protein (CRP) levels above the upper limit of normal
- The patient has sacroiliitis on magnetic resonance imaging (MRI)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
- The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.** If no, continue to #9.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.** If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for approval:

You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You are a candidate for systemic therapy (treatment that targets the entire body) or phototherapy (light therapy)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
- You meet ONE of the following:
  - You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) AND PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Bimzelx
  - You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA)
  - You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

If you have psoriatic arthritis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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BIMEKIZUMAB-BKZX

INITIAL CRITERIA (CONTINUED)

If you have non-radiographic axial spondyloarthritis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Bimzelx
  - You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
  - You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

If you have ankylosing spondylitis, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

If you have moderate to severe hidradenitis suppurativa, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, continue to #2.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, continue to #3.
If no, continue to #4.

Does the patient have coexistent moderate to severe plaque psoriasis (PsO)? (**Note:** For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.**

Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
- The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.**
If no, continue to #5.

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.** If no, continue to #6.

Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
- The patient has shown improvement in HS symptoms
- Bimzelx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.** If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BIMEKIZUMAB-BKZX (Bimzelx)** requires the following rule(s) be met for renewal:

You have ONE of the following:
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

(Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, renewal also requires:
- You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis) of at least 50 percent or more while on therapy
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

If you have psoriatic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

If you have non-radiographic axial spondyloarthritis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

(Renewal denial text continued on next page)

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BIMEKIZUMAB-BKZX

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe hidradenitis suppurativa, renewal also requires:
You have shown improvement in your hidradenitis suppurativa symptoms
You will NOT use Bimzelx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Bimzelx.

REFERENCES
Bimzelx [Prescribing Information]. Smyrna, GA: UCB, Inc.; November 2024.

Created: 10/23
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BINIMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BINIMETINIB	MEKTOVI	45040		GPI-10 (2153352000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
The patient has a BRAF V600E or V600K mutation, as detected by an FDA-approved test
Mektovi will be used in combination with Braftovi (encorafenib)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
If no, continue to #2.

Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has a BRAF V600E mutation, as detected by an FDA-approved test
Mektovi will be used in combination with Braftovi (encorafenib)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BINIMETINIB (Mektovi)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
- Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

If you have unresectable or metastatic melanoma, approval also requires:
- You have a BRAF V600E or V600K mutation (types of gene mutations), as detected by a Food and Drug Administration (FDA)-approved test
- Mektovi will be used in combination with Braftovi (encorafenib)

If you have metastatic non-small cell lung cancer, approval also requires:
- You are 18 years of age or older
- You have a BRAF V600E mutation (a type of gene mutation), as detected by a Food and Drug Administration (FDA)-approved test
- Mektovi will be used in combination with Braftovi (encorafenib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BINIMETINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mektovi.

REFERENCES

Mektovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; September 2024.

Created: 08/18
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BIRCH BARK EXTRACT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BIRCH BARK EXTRACT	FILSUVEZ	48746		GPI-10 (9094402000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of epidermolysis bullosa (EB) (ICD-10 Q81.9) and meet **ALL** of the following criteria?
The patient is 6 months of age or older
Filsuvez will be used for the treatment of wounds associated with dystrophic or junctional epidermolysis bullosa

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BIRCH BARK EXTRACT (Filsuvez)** requires the following rule(s) be met for approval:
You have epidermolysis bullosa (EB: a type of genetic skin disorder)
You are 6 months of age or older
Filsuvez will be used for the treatment of wounds associated with dystrophic or junctional epidermolysis bullosa (types of genetic skin disorders)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Filsuvez.

REFERENCES

Filsuvez [Prescribing Information]. Wahlstedt, Germany: Lichtenheldt GmbH Pharmazeutische Fabrik; May 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BLINATUMOMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BLINATUMOMAB	BLINCYTO	41612		GPI-10 (2135202000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the cancer minimal residual disease (MRD)-positive and the patient meets **ALL** of the following criteria?
The patient is in first or second complete remission
The patient has minimal residual disease (MRD) of at least 0.1%

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Is the cancer relapsed or refractory?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

Is the cancer Philadelphia chromosome-negative **AND** the patient meets the following criterion?
The patient is in the consolidation phase of multiphase chemotherapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BLINATUMOMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BLINATUMOMAB (Blincyto)** requires the following rule(s) be met for approval:

You have CD19 (a type of protein)-positive B-cell precursor acute lymphoblastic leukemia (ALL: a type of blood cancer)

You meet ONE of the following:

- You have minimal residual disease (MRD)-positive acute lymphoblastic leukemia (a small number of cancer cells remain after treatment), you are in first or second complete remission (no symptoms or signs of disease), AND you have minimal residual disease of at least 0.1 percent
- You have relapsed or refractory acute lymphoblastic leukemia (a type of blood cancer that has returned or did not respond to treatment)
- You have Philadelphia chromosome-negative acute lymphoblastic leukemia (a type of blood cancer) AND you are in the consolidation phase (treatment following initial therapy) of multiphase chemotherapy (cancer treatment that involves multiple courses of therapy)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Blincyto.

REFERENCES

Blincyto [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; June 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/22/24
Created: 02/15
Client Approval: 06/24
P&T Approval: 07/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BORTEZOMIB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BORTEZOMIB	VELCADE, BORUZU, BORTEZOMIB	25202		GPI-10 (2153601500)	

GUIDELINES FOR USE

Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #2.

Does the patient have a diagnosis of mantle cell lymphoma (ICD-10 Group C83.1) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BORTEZOMIB (Velcade, Boruzu)** requires the following rule(s) be met for approval:
You have ONE of the following:
Multiple myeloma (a type of blood cancer)
Mantle cell lymphoma (a type of blood cancer)
You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BORTEZOMIB (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Velcade or Boruzu.

REFERENCES

Velcade [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; August 2022.
Boruzu [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals; September 2024.

Created: 11/12
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOSENTAN	TRACLEER, BOSENTAN	22990		GPI-10 (4016001500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
The patient is 3 years of age or older
Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
The patient does NOT have idiopathic pulmonary fibrosis (IPF)
Tracleer will NOT be used concurrently with cyclosporine A or glyburide

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
62.5mg tablet: #2 per day.
125mg tablet: #2 per day.
32mg tablet for suspension: #4 per day.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BOSENTAN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BOSENTAN (Tracleer)** requires the following rule(s) be met for approval:
You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
You are 3 years of age and older
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
You do NOT have idiopathic pulmonary fibrosis (scarring of the lungs due to an unknown cause)
You will NOT use Tracleer concurrently (at the same time) with cyclosporine A or glyburide
Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
Mean pulmonary artery pressure (PAP) greater than 20 mmHg
Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSENTAN

RENEWAL CRITERIA

Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) **AND** meet the following criterion?
Tracleer will NOT be used concurrently with cyclosporine A or glyburide

If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
62.5mg tablet: #2 per day.
125mg tablet: #2 per day.
32mg tablet for suspension: #4 per day.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BOSENTAN (Tracleer)** requires the following rule(s) be met for renewal:
You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
You will NOT use Tracleer concurrently (at the same time) with cyclosporine A or glyburide

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tracleer.

REFERENCES

Tracleer [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 10/22
Client Approval: 06/24
P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOSUTINIB	BOSULIF, BOSUTINIB	39590		GPI-10 (2153181200)	

GUIDELINES FOR USE

Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) (ICD-10 Group C92.1)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the Ph+ CML in chronic phase (CP) **AND** the patient meets the following criterion?
The patient is 1 year of age or older

If yes, continue to #3.
If no, continue to #5.

Is the patient newly diagnosed (e.g., starting or previously started Bosulif treatment at the time of diagnosis)?

If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
500mg: #1 per day.
400mg: #1 per day.
100mg: #6 per day.
50mg: #1 per day.

If no, continue to #4.

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BOSUTINIB

GUIDELINES FOR USE (CONTINUED)

Does the patient have a resistance or intolerance to a prior therapy (e.g., Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib]) **AND** meet the following criterion?
The patient had a mutational analysis prior to initiation of therapy AND Bosulif is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
500mg: #1 per day.
400mg: #1 per day.
100mg: #6 per day.
50mg: #1 per day.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Is the Ph+ CML in accelerated phase (AP) or blast phase (BP), and the patient meets **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has a resistance or intolerance to a prior therapy (e.g., Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib])
The patient had a mutational analysis prior to initiation of therapy AND Bosulif is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
500mg: #1 per day.
400mg: #1 per day.
100mg: #6 per day.
50mg: #1 per day.

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BOSUTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT:

Our guideline named **BOSUTINIB (Bosulif)** requires the following rule(s) be met for approval:
You have Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML: a type of blood cell cancer)
If you have Philadelphia chromosome-positive chronic myelogenous leukemia in chronic phase (CP), approval also requires:
You are 1 year of age or older
You meet ONE of the following:
You are newly diagnosed (such as you are starting or previously started Bosulif treatment at the time your condition was identified)
You have a resistance (medication no longer works as well) or intolerance (side effect) to a prior therapy (such as Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib]); you had a mutational analysis (a type of lab test) prior to the start of therapy; AND Bosulif is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR- ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile
If you have Philadelphia chromosome-positive chronic myelogenous leukemia in accelerated phase (AP) or blast phase (BP), approval also requires:
You are 18 years of age or older
You have a resistance (medication no longer works as well) or intolerance (side effect) to a prior therapy (such as Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib])
You had a mutational analysis (a type of lab test) prior to the start of therapy; AND Bosulif is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bosulif.

REFERENCES

Bosulif [Prescribing Information]. New York, NY: Pfizer Inc.; March 2026.

Created: 09/12
Effective: 06/27/26 Client Approval: 06/26 P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BREMELANOTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BREMELANOTIDE ACETATE	VYLEESI	45878		GPI-10 (6217351510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Is Vyleesi (bremelanotide) a covered benefit?

If yes, continue to #2.
If no, guideline does not apply.

Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (ICD-10 F52.0) (also referred to as female sexual interest/arousal disorder [FSIAD] [ICD-10 F52.22] per DSM-5), as defined by **ALL** of the following criteria?
The patient has persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
The patient's HSDD is NOT a result of a co-existing medical or psychiatric condition, a problem within the relationship, or the effects of a medication or drug substance
The patient's HSDD symptom causes marked distress or interpersonal difficulty

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ALL** of the following criteria?
The patient is a premenopausal female
The patient is 18 years of age or older
The patient had a trial of or contraindication to bupropion
Vylessi will NOT be used concurrently with Addyi (flibanserin)

If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #2.4mL per month.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BREMELANOTIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for approval:

- You have acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD]) (a type of sexual disorder), as defined by ALL of the following:
  - You have persistently (continues to exist) or recurrently (continues to return) deficient (absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
  - Your HSDD (a type of sexual disorder) is NOT a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship, or the effects of a medication or drug substance
  - Your HSDD (a type of sexual disorder) symptom causes marked distress or interpersonal difficulty
- You are a premenopausal (before menopause) female
- You are 18 years of age or older
- You have tried or have a contraindication to (harmful for you to use) bupropion
- You will NOT use Vylessi concurrently (at the same time) with Addyi (flibanserin)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BREMELANOTIDE

RENEWAL CRITERIA

Does the patient meet **ALL** of the following criteria?

Vyleesi will NOT be used concurrently with Addyi (flibanserin)

The patient has demonstrated continued improvement in symptoms of hypoactive sexual desire disorder (HSDD)/female sexual interest/arousal disorder (FSIAD) (e.g., increased sexual desire, lessened distress)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.4mL per month.** If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for renewal:

You will NOT use Vyleesi concurrently (at the same time) with Addyi (flibanserin)

You have experienced continued improvement in symptoms of hypoactive sexual desire disorder (HSDD)/female sexual interest/arousal disorder (FSIAD) (a type of sexual disorder) (such as increased sexual desire, reduced distress)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyleesi.

REFERENCES

Vyleesi [Prescribing Information]. Cranbury, NJ: Palatin Technologies, Inc.; February 2021.

Created: 08/19
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRENSOCATIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRENSOCATIB	BRINSUPRI	50812		GPI-10 (4500150800)	

GUIDELINES FOR USE

Does the patient have a diagnosis of non-cystic fibrosis bronchiectasis (NCFB) **AND** meet the following criterion?
The patient is 12 years of age or older

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BRENSOCATIB (Brinsupri)** requires the following rule(s) be met for approval:
You have non-cystic fibrosis bronchiectasis (NCFB: a condition where your lungs' airway becomes damaged, widened, and thickened)
You are 12 years of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brinsupri.

REFERENCES

Brinsupri [Prescribing Information]. Bridgewater, NJ: f Insmed Incorporated; August 2025.

Created: 08/25
Effective: 09/08/25 Client Approval: 08/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRENTUXIMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRENTUXIMAB VEDOTIN	ADCETRIS	37879		GPI-10 (2135322020)	

GUIDELINES FOR USE

Does the patient have a diagnosis of classical Hodgkin lymphoma (cHL) (ICD-10 Group C81)?

If yes, continue #2.
If no, continue to #7.

Is the patient's cancer at stage III or IV and the patient meets **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has not been previously treated
Adcetris will be used in combination with doxorubicin, vinblastine, and dacarbazine

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Is the patient's cancer considered high-risk and the patient meets **ALL** of the following criteria?
The patient is 2 years of age or older
The patient has not been previously treated
Adcetris will be used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

Is the patient at high risk for relapse or disease progression post-autologous hematopoietic stem cell transplant (auto-HSCT) (defined as refractory, relapse within 12 months, or relapse at least 12 months with extranodal disease) and the patient meets **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has obtained complete remission (CR), partial remission (PR), or stable disease (SD) to most recent pre-auto-HSCT salvage therapy

If yes, **approve for 12 months by HICL or GPI-10**.
If no, continue to #5.

Has the patient's cancer relapsed **AND** the patient meets the following criterion?
The patient is 18 years of age or older

If yes, continue to #6.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BRENTUXIMAB

GUIDELINES FOR USE (CONTINUED)

Does the patient meet **ONE** of the following criteria?
The patient has failed an autologous hematopoietic stem cell transplant (auto-HSCT)
The patient is not an auto-HSCT candidate AND has failed at least two multi-agent chemotherapy regimens (e.g., ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Does the patient have a diagnosis of systemic anaplastic large cell lymphoma (sALCL) (ICD-10 Groups C84.6, C84.7) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #8.
If no, continue to #10.

Is the patient previously untreated **AND** Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #9.

Has the patient relapsed **AND** failed at least one multi-agent chemotherapy regimen (e.g., CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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BRENTUXIMAB

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma (ICD-10 C86.5) or PTCL not otherwise specified (ICD-10 Group C84.4), and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has not been previously treated
Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #11.

Does the patient have a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) (ICD-10 C86.6) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has received prior systemic therapy (e.g., CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], methotrexate)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #12.

Does the patient have a diagnosis of mycosis fungoides (MF) (Group C84.0) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer is CD30-positive
The patient has received prior systemic therapy (e.g., Istodax [romidepsin], methotrexate)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #13.

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BRENTUXIMAB

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of large B-cell lymphoma (LBCL) (ICD-10 Groups C83.3, C85.2), including diffuse large B-cell lymphoma (DLBCL) not other specified (ICD-10 Group C83.3), DLBCL arising from indolent lymphoma (ICD-10 Group C83.3), or high-grade B-cell lymphoma (HGBL), and meet **ALL** of the following criteria?
The patent is 18 years of age or older
The patient's cancer is relapsed or refractory
Adcetris will be used in combination with Revlimid (lenalidomide) AND a rituximab product (e.g., Rituxan [rituximab], Truxima [rituximab-abbs])
The patient has tried at least two lines of systemic therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
The patient is not eligible for auto-HSCT or chimeric antigen receptor (CAR) T-cell therapy (e.g., Yescarta [axicabtagene ciloleucel], Kymriah [tisagenlecleucel])

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

Our guideline named **BRENTUXIMAB (Adcetris)** requires the following rule(s) be met for approval:
You have ONE of the following:
Classical Hodgkin lymphoma (a type of blood cancer)
Systemic anaplastic large cell lymphoma (a type of blood cancer)
CD30-expressing peripheral T-cell lymphomas (a type of blood cancer)
Primary cutaneous anaplastic large cell lymphoma (a type of blood cancer)
Mycosis fungoides (a type of blood cancer affecting the skin)
Large B-cell lymphoma (LBCL), which includes diffuse large B-cell lymphoma (DLBCL) not other specified, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL) (types of blood cancer)
(Denial text continued on next page)

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BRENTUXIMAB

GUIDELINES FOR USE (CONTINUED)

If you have classical Hodgkin lymphoma, approval also requires ONE of the following:
- Your cancer is stage III or IV; you are 18 years of age or older; you have not been previously treated; AND Adcetris will be used in combination with doxorubicin, vinblastine, and dacarbazine
- Your cancer is considered high-risk; you are 2 years of age or older; you have not been previously treated; AND Adcetris will be used in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide
- You are at high risk for relapse (disease comes back) or disease progression (disease gets worse) after having autologous hematopoietic stem cell transplant (auto-HSCT) (defined as refractory [disease does not respond to treatment], relapse within 12 months, or relapse at least 12 months with extranodal [area outside of the lymph node] disease); you are 18 years of age or older; AND you have obtained complete/partial remission (little or no sign of cancer in your body), or stable disease to most recent pre-auto-HSCT salvage therapy
- Your cancer has relapsed; you are 18 years of age or older; AND you have failed autologous hematopoietic stem cell transplant (auto-HSCT: transplant cells are from your own body)
- Your cancer has relapsed; you are 18 years of age or older; you are not a candidate for auto-HSCT; AND you have failed at least two multi-agent chemotherapy regimens (such as ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])

If you have systemic anaplastic large cell lymphoma, approval also requires:
- You are 18 years of age or older
- You meet ONE of the following:
  - You have not been previously treated AND Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone
  - Your cancer has relapsed (disease that has returned) AND you have failed at least one multi-agent chemotherapy regimen (such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])

If you have CD30-expressing peripheral T-cell lymphomas, including angioimmunoblastic T-cell lymphoma or peripheral T-cell lymphoma not otherwise specified, approval also requires:
- You are 18 years of age or older
- You have not been previously treated
- Adcetris will be used in combination with cyclophosphamide, doxorubicin, and prednisone

(Denial text continued on next page)

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BRENTUXIMAB

GUIDELINES FOR USE (CONTINUED)

If you have primary cutaneous anaplastic large cell lymphoma, approval also requires:
- You are 18 years of age or older
- You have received prior systemic therapy (treatment that targets the entire body such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], methotrexate)

If you have mycosis fungoides, approval also requires:
- You are 18 years of age or older
- Your cancer is CD30 (a type of protein)-positive
- You have received prior systemic therapy (treatment that targets the entire body such as Istodax [romidepsin], methotrexate)

If you have large B-cell lymphoma, which includes diffuse large B-cell lymphoma not other specified, diffuse large B-cell lymphoma arising from indolent lymphoma, or high-grade B-cell lymphoma, approval also requires:
- You are 18 years of age or older
- Your cancer is relapsed (disease that has returned) or refractory (did not respond to treatment)
- Adcetris will be used in combination with Revlimid (lenalidomide) AND a rituximab product (such as Rituxan [rituximab], Truxima [rituximab-abbs])
- You have has tried at least two lines of systemic therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
- You are not eligible for autologous hematopoietic stem cell transplantation (auto-HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells) or chimeric antigen receptor (CAR) T-cell therapy (such as Yescarta [axicabtagene ciloleucel], Kymriah [tisagenlecleucel])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcetris.

REFERENCES

Adcetris [Prescribing Information]. Bothell, WA: Seagen Inc.; February 2025.

Created: 09/11
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRIGATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRIGATINIB	ALUNBRIG	44226		GPI-10 (2153051000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet ALL of the following criteria?
The patient is 18 years of age or older
The patient's tumor is positive for anaplastic lymphoma kinase (ALK) fusion oncogene, as detected by an FDA-approved test

If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
30 mg: #120 per 30 days.
90 mg: #30 per 30 days.
180 mg: #30 per 30 days.
90 mg-180 mg initiation pack: #30 per 30 days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BRIGATINIB (Alunbrig)** requires the following rule(s) be met for approval:
You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
You are 18 years of age or older
Your tumors are positive for anaplastic lymphoma kinase (ALK) fusion oncogene (a type of abnormal gene), as detected by a Food and Drug Administration (FDA)-approved test

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alunbrig.

REFERENCES

Alunbrig [Prescribing Information]. Cambridge, MA: Ariad Pharmaceuticals; October 2024.

Created: 07/17
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BRODALUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BRODALUMAB	SILIQ	44102		GPI-10 (9025052000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, face, or scalp
- The patient has been counseled on and expresses understanding of the risk of suicidal ideation and behavior
- Siliq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Taltz (ixekizumab)
  - Sotyktu (deucravacitinib)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Icotyde (icotrokinra)

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, continue to #2.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

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BRODALUMAB

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?

- The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3mL per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #6mL per 28 days.)**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for approval:
You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
You are 18 years of age or older
Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp
You have been counseled on and express an understanding of the risk of suicidal thoughts and behavior
You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
(Initial denial text continued on next page)

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BRODALUMAB

INITIAL CRITERIA (CONTINUED)

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
- Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Enbrel (etanercept)
- Otezla (apremilast)
- Taltz (ixekizumab)
- Sotyktu (deucravacitinib)
- Bimzelx (bimekizumab-bkzx)
- Adalimumab-ryvk/adalimumab-aaty
- Icotyde (icotrokinra)

You meet ONE of the following:
- You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
- You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) AND PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
- You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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BRODALUMAB

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?

- The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
- The patient has NOT developed or reported worsening depressive symptoms or suicidal ideation and behaviors
- Siliq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Taltz (ixekizumab)
  - Sotyktu (deucravacitinib)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Icotyde (icotrokinra)

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3mL per 28 days.**
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BRODALUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BRODALUMAB (Siliq)** requires the following rule(s) be met for renewal:
You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis [a type of skin condition]) of at least 50 percent or more
You have NOT developed or reported worsening depressive symptoms or suicidal thoughts and behaviors while on treatment with Siliq
You will NOT use Siliq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
Tremfya (guselkumab)
Skyrizi (risankizumab-rzaa)
Enbrel (etanercept)
Otezla (apremilast)
Taltz (ixekizumab)
Sotyktu (deucravacitinib)
Bimzelx (bimekizumab-bkzx)
Adalimumab-ryvk/adalimumab-aaty
Icotyde (icotrokinra)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Siliq.

REFERENCES

Siliq [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; February 2026.

Created: 01/17
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 01/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BROLUCIZUMAB-DBLL (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BROLUCIZUMAB-DBLL	BEOVU	46051		GPI-10 (8665502520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
Beovu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea, Lucentis, Susvimo)

If yes, **approve for 4 months by HICL or GPI-10 for 3 fills with the following quantity limits:**
For one eye: #0.05mL per 28 days.
For two eyes: #0.1mL per 28 days.

If no, continue to #2.

Does the patient have a diagnosis of diabetic macular edema (DME) and meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
Beovu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea, Lucentis, Vabysmo)

If yes, **approve for 8 months by HICL or GPI-10 for 5 fills with the following quantity limits:**
For one eye: #0.05mL per 42 days.
For two eyes: #0.1mL per 42 days.

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BROLUCIZUMAB-DBLL (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BROLUCIZUMAB-DBLL (Beovu)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
- Neovascular (wet) age-related macular degeneration (nAMD: a type of eye disease)
- Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)

If you have neovascular age-related macular degeneration, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You are NOT using Beovu at the same time with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea, Lucentis, Susvimo)

If you have diabetic macular edema, approval also requires:
- Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
- You are NOT using Beovu at the same time with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea, Lucentis, Vabysmo)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) and meet **ALL** of the following criteria?
- The patient has maintained or improved visual acuity
- Beovu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea, Lucentis, Susvimo)

If yes, **approve for 12 months by HICL or GPI-10 with the following quantity limits:**
For one eye: #0.05mL per 56 days.
For two eyes: #0.1mL per 56 days.

If no, continue to #2.

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BROLUCIZUMAB-DBLL (NSA)

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of diabetic macular edema (DME) and meet **ALL** of the following criteria?
The patient has maintained or improved visual acuity
Beovu will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea, Lucentis, Vabysmo)

If yes, **approve for 12 months by HICL or GPI-10 with the following quantity limits:**
For one eye: #0.05mL per 56 days.
For two eyes: #0.1mL per 56 days.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BROLUCIZUMAB-DBLL (Beovu)** requires the following rule(s) be met for renewal:
You have ONE of the following diagnoses:
Neovascular (wet) age-related macular degeneration (nAMD: a type of eye disease)
Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
If you have neovascular age-related macular degeneration, renewal also requires:
You have maintained or improved visual acuity (vision clarity or sharpness)
You are NOT using Beovu at the same time with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea, Lucentis, Susvimo)
If you have diabetic macular edema, renewal also requires:
You have maintained or improved visual acuity (vision clarity or sharpness)
You are NOT using Beovu at the same time with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea, Lucentis, Vabysmo)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BROLUCIZUMAB-DBLL (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Beovu.

REFERENCES

Beovu [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 10/19
Client Approval: 09/22
P&T Approval: 07/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - ORTIKOS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	ORTIKOS		46496 46497	GPI-14 (22100012007025, 22100012007030)	

GUIDELINES FOR USE

Does the patient have a diagnosis of mild to moderate active Crohn's disease (ICD-10 Group K50) and meet **ALL** of the following criteria?
The patient is 8 years of age or older
The patient had a trial of generic budesonide 3 mg capsules, OR the patient cannot tolerate the pill burden associated with the generic product

If yes, **approve for 6 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**

If no, continue to #2.

Does the patient have a diagnosis of mild to moderate Crohn's disease (ICD-10 Group K50) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Ortikos is being used for the maintenance of clinical remission
The patient had a trial of generic budesonide 3 mg capsules, OR the patient cannot tolerate the pill burden associated with the generic product

If yes, **approve for 6 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUDESONIDE - ORTIKOS** requires the following rule(s) be met for approval:
You have mild to moderate Crohn's disease (a type of bowel disorder)
If you have mild to moderate active Crohn's disease, approval also requires:
You are 8 years of age or older
You have tried generic budesonide 3 mg capsules OR you cannot tolerate the pill burden associated with the generic product
(Denial text continued on the next page)

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BUDESONIDE - ORTIKOS

GUIDELINES FOR USE (CONTINUED)

If you have mild to moderate Crohn's disease, approval also requires:

- You are 18 years of age or older
- Ortikos is being used for the maintenance of clinical remission (signs and symptoms of disease have improved or disappeared)
- You have tried generic budesonide 3 mg capsules, OR you cannot tolerate the pill burden associated with the generic product

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ortikos.

REFERENCES

Ortikos [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc. June 2024.

Created: 11/20
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE - TARPEYO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	TARPEYO		51745	GPI-14 (22100012006520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a nephrologist
- The patient's diagnosis is confirmed by a renal biopsy
- The patient has a progressively declining glomerular filtration rate (GFR) and/or worsening proteinuria (e.g., greater than 1 gram protein/24-hour urine collection or UPCR [urine protein to creatinine ratio] of at least 1 g/g)
- The patient has an eGFR of at least 35 mL/min/1.73m^2
- The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes

If yes, **approve for 9 months by GPID or GPI-14 with a quantity limit of #4 per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for approval:
- You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
- Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
- You have a progressively declining glomerular filtration rate (GFR: a tool for evaluating kidney function) and/or worsening proteinuria (increased levels of protein in the urine, such as greater than 1 gram protein in a 24-hour urine collection or at least 1 g/g urine protein to creatinine ratio [UPCR: a test that measures the amount of protein in urine])

(Initial denial text continued on the next page)

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BUDESONIDE - TARPEYO

INITIAL CRITERIA (CONTINUED)

You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 35 mL/min/1.73m^2
You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes

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BUDESONIDE - TARPEYO

RENEWAL CRITERIA

Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ONE** of the following criteria?
The patient has improved or stable kidney function compared to baseline
The patient has a reduction in proteinuria

If yes, **approve for 9 months by GPID or GPI-14 with a quantity limit of #4 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUDESONIDE - TARPEYO** requires the following rule(s) be met for renewal:
You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
You have improved or stable kidney function compared to baseline (before starting Tarpeyo)
OR you have a reduction in proteinuria (lowered levels of protein in the urine)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarpeyo.

REFERENCES

Tarpeyo [Prescribing Information]. Stockholm, Sweden: Calliditas Therapeutics AB; June 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE-EOHILIA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	EOHILIA		55273	GPI-14 (22100012001820)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ALL** of the following criteria?
The patient is 11 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist or allergist
The patient has at least 15 eosinophils/hpf in the esophagus as confirmed by a biopsy
The patient had a trial of or contraindication to one inhaled corticosteroid (e.g., Flovent [fluticasone], Pulmicort [budesonide]) OR one generic proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole)

If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUDESONIDE-EOHILIA** requires the following rule(s) be met for approval:
You have eosinophilic esophagitis (a type of immune system disorder)
You are 11 years of age or older
Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or allergist (a type of allergy doctor)
You have at least 15 eosinophils/high powered field (a type of lab test) in the esophagus as confirmed by a biopsy (removal of cells or tissue from the body for examination)
You have tried or have a contraindication to (harmful for you to use) one inhaled corticosteroid (such as Flovent [fluticasone], Pulmicort [budesonide]) OR one proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE-EOHILIA

RENEWAL CRITERIA

Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ONE** of the following criteria?
There is less than 15 eosinophils/hpf in the esophagus after treatment with Eohilia
The patient has experienced an improvement in dysphagia compared to baseline

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUDESONIDE-EOHILIA** requires the following rule(s) be met for renewal:
You have eosinophilic esophagitis (EoE: a type of immune system disorder)
You meet ONE of the following:
- You have less than 15 eosinophils/high powered field (eos/hpf: a type of lab test) in the esophagus after treatment with Eohilia
- You have experienced an improvement in dysphagia (difficulty swallowing) compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eohilia.

REFERENCES

Eohilia [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; May 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 02/24
Client Approval: 06/24
P&T Approval: 07/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BULEVIRTIDE-GMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BULEVIRTIDE ACETATE-GMOD	HEPCLUDEX	48141		GPI-10 (1235402001)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of chronic hepatitis delta virus (HDV) (ICD-10 B18.0) and meet **ALL** of the following criteria?

The patient is 18 years of age or older

The patient has compensated cirrhosis OR does not have cirrhosis

Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in treatment of hepatitis (e.g., hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes)

The patient has a positive serum anti-HDV antibody test OR a positive serum/plasma HDV RNA PCR

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: Our guideline named **BULEVIRTIDE-GMOD (Hepcludex)** requires the following rule(s) be met for approval:

You have chronic (long-term) hepatitis delta virus (HDV: liver inflammation caused by a type of virus)

You are 18 years of age or older

You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) OR you do not have cirrhosis (liver damage or scarring)

Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), physician specializing in treatment of hepatitis (liver inflammation) (such as a hepatologist [a type of liver doctor]), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes)

You have a positive serum anti-HDV (hepatitis delta virus) antibody test (a type of blood test) OR a positive serum/plasma HDV RNA PCR (a type of blood test)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BULEVIRTIDE-GMOD

RENEWAL CRITERIA

Does the patient have a diagnosis of chronic hepatitis delta virus (HDV) (ICD-10 B18.0) and meet **ALL** of the following criteria?

The patient has compensated cirrhosis OR does not have cirrhosis

The patient had a virological or biochemical response (e.g., undetectable HDV RNA or a decrease by 2 log10 IU/mL from baseline or ALT normalization or a trend towards these items)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: Our guideline named **BULEVIRTIDE-GMOD (Hepcludex)** requires the following rule(s) be met for renewal:

You have chronic (long-term) hepatitis delta virus (HDV: liver inflammation caused by a type of virus)

You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) OR you do not have cirrhosis (liver damage or scarring)

You had a virological or biochemical response (measures that show Hepcludex therapy is effective, such as an undetectable HDV RNA or a decrease by 2 log10 IU/mL from baseline [a type of lab test that shows a suppressed or reduced viral load from before start of treatment] or alanine transaminase [ALT: a type of liver enzyme test] normalization or a trend towards these items)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hepcludex.

REFERENCES

Hepcludex [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; May 2026.

Created: 06/26
Effective: 08/01/26 DMC Approval: 07/21/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUMETANIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUMETANIDE	ENBUMYST	03664		GPI-10 (3720001000)	ROUTE = NASAL

GUIDELINES FOR USE

Does the patient have a diagnosis of edema (ICD-10 Group R60) associated with congestive heart failure, hepatic disease or renal disease (including nephrotic syndrome) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a cardiologist, nephrologist, hepatologist, or gastroenterologist
The patient has a contraindication to or is unable to swallow bumetanide tablets

If yes, **approve for 30 days by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUMETANIDE** (**Enbumyst**) requires the following rule(s) be met for approval:
You have edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), hepatic (liver) disease or renal (kidney) disease (including nephrotic syndrome [a type of kidney disorder])
You are 18 years of age or older
Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), hepatologist (a type of liver doctor), or gastroenterologist (doctor who treats digestive conditions)
You have a contraindication to (harmful for you to use) or are unable to swallow bumetanide tablets

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enbumyst.

REFERENCES

Enbumyst [Prescribing Information]. Henderson, NV: Corstasis Therapeutics; September 2025.

Created: 10/25
Effective: 10/20/25 Client Approval: 10/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE EXTENDED-RELEASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUPRENORPHINE	SUBLOCADE		44186 44187	GPI-14 (6520001000E530, 6520001000E520)	

GUIDELINES FOR USE

Does the patient have a diagnosis of moderate to severe opioid use disorder (ICD-10 Group F11)
AND meet the following criterion?
The patient initiated treatment with a single dose of a transmucosal buprenorphine product (e.g., Suboxone [buprenorphine/naloxone], Zubsolv [buprenorphine/naloxone]) OR is already being treated with buprenorphine

If yes, **approve for 12 months by GPID or GPI-14 as follows:**
INITIAL REQUESTS:
FIRST APPROVAL: Approve all strengths for 1 month by GPID or GPI-14 as follows:
100 mg/0.5 mL syringe: #0.5 mL per 30 days.
300 mg/1.5 mL syringe: #3 mL per 30 days.
SECOND APPROVAL: Approve the requested strength for 11 months by GPID or GPI- 14 as follows (please enter a start date of 1 MONTH AFTER the START date of the first approval):
100 mg/0.5 mL syringe: #0.5 mL per 30 days.
300 mg/1.5 mL syringe: #1.5 mL per 30 days.
SUBSEQUENT REQUESTS:
Approve the requested strength for 12 months by GPID or GPI-14 as follows:
100 mg/0.5 mL syringe: #0.5 mL per 30 days.
300 mg/1.5 mL syringe: #1.5 mL per 30 days.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUPRENORPHINE EXTENDED-RELEASE (Sublocade)** requires the following rule(s) be met for approval:
You have moderate to severe opioid use disorder (misuse of a type of pain medication)
You started treatment with a single dose of a transmucosal (medication that enters the body through a mucous layer like those in the mouth) buprenorphine product (such as Suboxone [buprenorphine/naloxone], Zubsolv [buprenorphine/naloxone]), OR you are already being treated with buprenorphine

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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BUPRENORPHINE EXTENDED-RELEASE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sublocade.

REFERENCES

Sublocade [Prescribing Information]. North Chesterfield, VA: Indivior, Inc.; February 2025.

Created: 05/18
Effective: 03/17/25 Client Approval: 03/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BUROSUMAB-TWZA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUROSUMAB-TWZA	CRYSVITA	44867		GPI-10 (3090951060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of X-linked hypophosphatemia (XLH) confirmed by **ONE** of the following criteria?
- The patient has XLH symptoms (e.g., osteomalacia, excessive fractures, bowed legs, impaired growth) and ONE of the following:
  - The patient has a serum phosphate level of < 3.2 mg/dL in pediatric patients or <2.5 mg/dL in adults with normal vitamin D levels
  - The patient has shown hyperexpression of FGF23 protein on assay
  - The patient possesses family history of XLH
- Genotyping confirmation of the *PHEX* mutation causative of XLH

If yes, continue to #2.
If no, continue to #4.

Does the patient meet **ALL** of the following criteria?
- The patient is 6 months of age or older
- Therapy is prescribed by or in consultation with an endocrinologist, nephrologist, orthopedic surgeon, or medical geneticist
- The patient is NOT on concurrent oral phosphate salt or active vitamin D analog supplementation (e.g., calcitriol, paricalcitol)

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient had a trial of or failure to the clinical standard of care therapy: phosphate/vitamin D analog therapy
- The patient's disease condition, severity, and/or other variables indicate phosphate/vitamin D analog therapy is not preferable/advisable for this patient compared to anticipated outcomes with Crysvita

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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BUROSUMAB-TWZA

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) confirmed by the following criterion?
- The patient has TIO symptoms (e.g., osteomalacia, excessive fractures, muscle weakness, fatigue, bone pain)

  If yes, continue to #5.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist, nephrologist, orthopedic surgeon, or medical geneticist
- The tumors cannot be curatively resected or localized
- The patient has discontinued oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, etc.) at least 1 week prior to Crysvita initiation

  If yes, continue to #6.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient had a trial of or failure to the clinical standard of care therapy: phosphate/vitamin D analog therapy
- The patient's disease condition, severity, and/or other variables indicate phosphate/vitamin D analog therapy is not preferable/advisable for this patient compared to anticipated outcomes with Crysvita

  If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #12mL per 28 days.**
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

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BUROSUMAB-TWZA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUROSUMAB-TWZA (Crysvita)** requires the following rule(s) be met for approval:
You have ONE of the following diagnoses:
- X-linked hypophosphatemia (XLH: inherited disorder with low phosphate blood levels)
- Fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO: a rare disease characterized by the development of tumors that cause weakened and softened bones. The tumors release hormones known as fibroblast growth factor 23 that lowers your phosphate levels)

If you have X-linked hypophosphatemia, approval also requires:
- Your diagnosis is confirmed by ONE of the following:
  - You have XLH symptoms such as osteomalacia (bone softening), excessive fractures, bowed legs, impaired growth and ONE of the following:
    - If you are less than 18 years of age, your serum phosphate level is less than 3.2 mg/dL with normal vitamin D levels
    - If you are 18 years of age or older, your serum phosphate level is less than 2.5 mg/dL with normal vitamin D levels
    - You have more than normal amount of FGF23 protein on assay (type of lab analysis)
    - You have a family history of X-linked hypophosphatemia
  - You have a *PHEX* mutation (Phosphate-regulating neutral endopeptidase, X-linked) confirmed by a genotyping (type of test)
- You are 6 months of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor), nephrologist (kidney doctor), orthopedic surgeon (surgeon that deals with skeletal deformities), or medical geneticist
- You will not be taking oral phosphate salt or active vitamin D analog supplementation with the requested medication
- You meet ONE of the following:
  - You had a trial of or failure (drug did not work) to the clinical standard of care therapy: phosphate/vitamin D analog therapy (such as calcitriol, paricalcitol)
  - Your disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for you compared to anticipated outcomes with Crysvita

(Initial denial text continued on next page)

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BUROSUMAB-TWZA

INITIAL CRITERIA (CONTINUED)

If you have FGF23-related hypophosphatemia in tumor-induced osteomalacia, approval also requires:

- Your diagnosis is confirmed by the following:
  - You have symptoms of tumor-induced osteomalacia (such as osteomalacia [softening of the bones], excessive fractures, muscle weakness, fatigue, bone pain)
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor), nephrologist (kidney doctor), orthopedic surgeon (surgeon that deals with skeletal deformitis), or medical geneticist
- Your tumors cannot be curatively resected (surgically removed) or localized
- You have stopped oral phosphate and/or active vitamin D analogs (such as calcitriol, paricalcitol) at least 1 week prior to starting Crysvita
- You meet ONE of the following:
  - You had a trial of or failure (drug did not work) to the clinical standard of care therapy: phosphate/vitamin D analog therapy
  - Your disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for you compared to anticipated outcomes with Crysvita

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BUROSUMAB-TWZA

RENEWAL CRITERIA

Does the patient have a diagnosis of X-linked hypophosphatemia (XLH) **AND** meet the following criterion?
The patient has achieved normal blood phosphate levels as defined by reference range for age

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
If no, continue to #2.

Does the patient have a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) **AND** meet the following criterion?
The patient has achieved normalization of fasting serum phosphate levels (e.g., around or above the lower limit of the reference range for age and below 5 mg/dL)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #12mL per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUROSUMAB-TWZA (Crysvita)** requires the following rules be met for renewal:
You have ONE of the following diagnoses:
- X-linked hypophosphatemia (XLH; inherited disorder with low phosphate blood levels)
- Fibroblast growth factor 23 (FGF23) -related hypophosphatemia in tumor-induced osteomalacia (TIO: a rare disease characterized by the development of tumors that cause weakened and softened bones. The tumors release hormones known as fibroblast growth factor 23 that lowers your phosphate levels)

If you have X-linked hypophosphatemia, renewal also requires:
- You have achieved normal blood phosphate levels as defined by the reference range for your age

If you have FGF23-related hypophosphatemia in tumor-induced osteomalacia, renewal also requires:
- You have achieved normal fasting blood phosphate levels (around or above the lower end of the reference range for age and below 5 mg/dL)

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BUROSUMAB-TWZA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Crysvita.

REFERENCES

Crysvita [Prescribing Information]. Princeton, NJ: Kyowa Kirin, Inc.; August 2025.

Created: 08/18
Effective: 07/22/26 Client Approval: 07/26 P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - BERINERT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	BERINERT	18568		GPI-10 (8580202200)	FDB & MEDI-SPAN: BRAND = BERINERT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- Berinert will be used for the treatment of acute attacks of hereditary angioedema
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Berinert will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for 12 months by NDC.**
If no, continue to #3.

Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
- The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
- Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

If yes, **approve for 12 months by NDC.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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C1 ESTERASE INHIBITOR - BERINERT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - BERINERT** requires the following rule(s) be met for approval:

- You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- Berinert will be used for the treatment of acute (sudden and severe) attacks of hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
- You will NOT use Berinert concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])
- You meet ONE of the following:
  - You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
  - You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema: a type of gene condition with severe body swelling) as confirmed by ALL of the following:
    - You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
    - Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - BERINERT

RENEWAL CRITERIA

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
The patient has experienced a reduction in the severity or duration of HAE attacks
Berinert will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

If yes, **approve for 12 months by NDC.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - BERINERT** requires the following rule(s) be met for renewal:
You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
You have experienced a reduction (decrease) in the severity or duration of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
You will NOT use Berinert concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Ruconest [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Berinert.

REFERENCES
Berinert [Prescribing Information]. Kankakee, IL: CSL Behring LLC; September 2021.

Created: 04/09
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - CINRYZE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	CINRYZE	18568		GPI-10 (8580202200)	BRAND = CINRYZE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Cinryze will be used for prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Cinryze will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for 12 months for all NDCs with a quantity limit of #40 vials per 28 days.**
If no, continue to #3.

Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
- The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
- Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

If yes, **approve for 12 months for all NDCs with a quantity limit of #40 vials per 28 days.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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C1 ESTERASE INHIBITOR - CINRYZE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - CINRYZE** requires the following rule(s) be met for approval:

- You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- You are 6 years of age or older
- Cinryze will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
- Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
- You will NOT use Cinryze concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])
- You meet ONE of the following:
  - You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
  - You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema: a type of gene condition with severe body swelling) as confirmed by ALL of the following:
    - You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
    - Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - CINRYZE

RENEWAL CRITERIA

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient has experienced an improvement in HAE attacks (reductions in attack frequency or attack severity) compared to baseline
- Cinryze will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

If yes, **approve for 12 months for all NDCs with a quantity limit of #40 vials per 28 days.** If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - CINRYZE** requires the following rule(s) be met for renewal:
- You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- You have experienced an improvement in hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
- You will NOT use Cinryze concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cinryze.

REFERENCES

Cinryze [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; November 2024.

Created: 10/22
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - HAEGARDA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR	HAEGARDA	18568		GPI-10 (8580202200)	BRAND = HAEGARDA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Haegarda will be used for prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Haegarda will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
If no, continue to #3.

Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
- The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
- Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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C1 ESTERASE INHIBITOR - HAEGARDA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - HAEGARDA** requires the following rule(s) be met for approval:

- You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- You are 6 years of age or older
- Haegarda will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
- Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
- You will NOT use Haegarda concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])
- You meet ONE of the following:
  - You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
  - You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
    - You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
    - Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - HAEGARDA

RENEWAL CRITERIA

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient has experienced an improvement in HAE attacks (reductions in attack frequency or attack severity) compared to baseline
- Haegarda will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - HAEGARDA** requires the following rule(s) be met for renewal:
- You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- You have experienced an improvement in hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
- You will NOT use Haegarda concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Cinryze [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Haegarda.

REFERENCES

Haegarda [Prescribing Information]. Kankakee, IL: CSL Behring LLC; January 2022.

Created: 10/22
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

C1 ESTERASE INHIBITOR - RUCONEST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
C1 ESTERASE INHIBITOR, RECOMB	RUCONEST	37766		GPI-10 (8580202210)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- Ruconest will be used for the treatment of acute attacks of hereditary angioedema
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Ruconest will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 vials per fill.**
If no, continue to #3.

Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
- The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
- Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 vials per fill.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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C1 ESTERASE INHIBITOR - RUCONEST

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for approval:

- You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- Ruconest will be used for the treatment of acute (sudden and severe) attacks of hereditary angioedema (HAE: a type of gene condition with severe body swelling)
- Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
- You will NOT use Ruconest concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])
- You meet ONE of the following:
  - You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
  - You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
    - You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
    - Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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C1 ESTERASE INHIBITOR - RUCONEST

RENEWAL CRITERIA

Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
The patient has experienced a reduction in the severity or duration of HAE attacks
Ruconest will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 vials per fill.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **C1 ESTERASE INHIBITOR - RUCONEST** requires the following rule(s) be met for renewal:
You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
You have experienced a reduction (decrease) in the severity or duration of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
You will NOT use Ruconest concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Firazyr [icatibant], Kalbitor [ecallantide])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ruconest.

REFERENCES

Ruconest [Prescribing Information]. Warren, NJ: Pharming Healthcare Inc.; April 2020.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CABOZANTINIB CAPSULE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CABOZANTINIB S-MALATE	COMETRIQ		33903 33904 33905	GPI-14 (21533010106460, 21533010106470, 21533010106480)	

GUIDELINES FOR USE

Does the patient have a diagnosis of progressive, metastatic medullary thyroid cancer (MTC) (ICD- 10 C73)?

If yes, **approve all daily dose packs for 12 months by GPID or GPI-14 with a quantity limit of #112 per 28 days.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CABOZANTINIB CAPSULE (Cometriq)** requires the following rule be met for approval:
You have progressive, metastatic medullary thyroid cancer (a type of thyroid cancer that has spread to other parts of the body)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cometriq.

REFERENCES

Cometriq [Prescribing Information]. Alameda, CA: Exelixis, Inc.; August 2023.

Created: 01/13
Effective: 01/01/26 Client Approval: 04/25 P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CABOZANTINIB TABLET

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CABOZANTINIB S-MALATE	CABOMETYX		41146 41147 41148	GPI-14 (21533010100320, 21533010100330, 21533010100340)	

GUIDELINES FOR USE

Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ONE** of the following criteria?
Cabometyx will be used as a single agent
Cabometyx will be used in combination with Opdivo (nivolumab) or Opdivo Qvantig (nivolumab-hyaluronidase-nvhy)

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
60mg: #1 per day.
40mg: #2 per day.
20mg: #1 per day.

If no, continue to #2.

Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) **AND** meet the following criterion?
The patient has been previously treated with Nexavar (sorafenib)

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
60mg: #1 per day.
40mg: #2 per day.
20mg: #1 per day.

If no, continue to #3.

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CABOZANTINIB TABLET

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of locally advanced or metastatic differentiated thyroid cancer (DTC) (ICD-10 C73) and meet **ALL** of the following criteria?
The patient is 12 years of age or older
The patient has disease progression following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (e.g., Lenvima [lenvatinib])
The patient is radioactive iodine-refractory or ineligible

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
60mg: #1 per day.
40mg: #2 per day.
20mg: #1 per day.

If no, continue to #4.

Does the patient have a diagnosis of pancreatic or extra-pancreatic neuroendocrine tumor (pNET or epNET) (ICD-10 C25.4, Group C7A) and meet **ALL** of the following criteria?
The patient is 12 years of age or older
The tumor is unresectable, locally advanced or metastatic, and well-differentiated
The tumor has been previously treated

If yes**, approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit of #1 per day.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CABOZANTINIB TABLET (Cabometyx)** requires the following rule(s) be met for approval:
You have ONE of the following:
Advanced renal cell carcinoma (RCC: a type of kidney cancer)
Hepatocellular carcinoma (HCC: a type of liver cancer)
Locally advanced or metastatic differentiated thyroid cancer (DTC: a type of thyroid cancer that has spread to nearby tissue/lymph nodes or to other parts of the body)
Pancreatic neuroendocrine tumor (pNET: tumor that began in the pancreas)
Extra-pancreatic neuroendocrine tumor (epNET: tumor that began outside of the pancreas)
(Denial text continued on next page)

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CABOZANTINIB TABLET

GUIDELINES FOR USE (CONTINUED)

If you have advanced renal cell carcinoma, approval also requires ONE of the following:
Cabometyx will be used as a single agent (used alone)
Cabometyx will be used in combination with Opdivo (nivolumab) or Opdivo Qvantig (nivolumab-hyaluronidase-nvhy)

If you have hepatocellular carcinoma, approval also requires:
You have been previously treated with Nexavar (sorafenib)

If you have locally advanced or metastatic differentiated thyroid cancer, approval also requires:
You are 12 years of age or older
You have disease progression (worsening) following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy (such as Lenvima [lenvatinib])
You are radioactive iodine-refractory (resistant to) or ineligible

If you have a pancreatic or extra-pancreatic neuroendocrine tumor, approval also requires:
You are 12 years of age or older
Your tumor is unresectable (unable to remove by surgery), locally advanced or metastatic (cancer that has spread to nearby tissue/lymph nodes or to other parts of the body), and well-differentiated
Your tumor has been previously treated

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cabometyx.

REFERENCES
Cabometyx [Prescribing Information]. Alameda, CA: Exelixis, Inc.; October 2025.

Created: 01/13
Effective: 03/04/26 Client Approval: 03/26 P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CALASPARGASE PEGOL-MKNL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CALASPARGASE PEGOL-MKNL	ASPARLAS	45566		GPI-10 (2125003050)	

GUIDELINES FOR USE

Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) and meet **ALL** of the following criteria?
The patient is 1 month to 21 years of age
Asparlas will be used as a component of a multi-agent chemotherapeutic regimen

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CALASPARGASE PEGOL-MKNL (Asparlas)** requires the following rule(s) be met for approval:
You have acute lymphoblastic leukemia (ALL: a type of blood cancer)
You are 1 month to 21 years of age
Asparlas will be used as a part of a chemotherapeutic (medications used to treat cancer) plan that contains multiple medications

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Asparlas.

REFERENCES

Asparlas [Prescribing Information]. Boston, MA: Servier Pharmaceuticals LLC; November 2023.

Created: 10/19
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 04/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANAKINUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CANAKINUMAB/PF	ILARIS	36497		GPI-10 (6646002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) (ICD-10 M04.2), including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), and meet **ALL** of the following criteria?
- The patient is 4 years of age or older
- The patient has genetic testing for gain-of-function mutations in the *NLRP3* gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins)
- The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
- Ilaris will NOT be used concurrently with another systemic biologic (e.g., Arcalyst [rilonacept]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CAPS, including FCAS or MWS

If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
If no, continue to #2.

Does the patient have a diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) (ICD-10 M04.1) **AND** meet the following criterion?
- Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of TRAPS

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, continue to #3.

Does the patient have a diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (ICD-10 M04.1) **AND** meet the following criterion?
- Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HIDS/MKD

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, continue to #4.

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CANAKINUMAB

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of Familial Mediterranean Fever (FMF) (ICD-10 M04.1) **AND** meet the following criterion?
- Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of FMF

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, continue to #5.

Does the patient have a diagnosis of Adult-Onset Still's Disease (AOSD) (ICD-10 M06.1) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
- Ilaris will NOT be used concurrently with another systemic biologic (e.g., Kineret [anakinra]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of AOSD
- The patient had a trial of or contraindication to the preferred agent: Kineret (anakinra) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, continue to #6.

Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
- Ilaris will NOT be used concurrently with another systemic biologic (e.g., Actemra [tocilizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
- The patient had a trial of or contraindication to the following preferred agent: Tyenne (tocilizumab-aazg)
  [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, continue to #7.

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CANAKINUMAB

INITIAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of gout flares (ICD-10 Group M10) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of gout flares

If yes, continue to #8.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Has the patient had a trial of or contraindication to **ALL** of the following?
- Colchicine
- An NSAID (non-steroidal anti-inflammatory drug) (e.g., ibuprofen, naproxen, indomethacin)
- A corticosteroid (e.g., triamcinolone, methylprednisolone, prednisone, prednisolone)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Cryopyrin-Associated Periodic Syndromes (CAPS: a type of immune disorder), including Familial Cold Auto-inflammatory Syndrome (FCAS: a type of immune disorder) or Muckle-Wells Syndrome (MWS: a type of immune disorder)
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: a type of genetic disease)
- Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (types of genetic disorders)
- Familial Mediterranean Fever (FMF: a type of genetic disorder)
- Adult-Onset Still's Disease (AOSD: an autoinflammatory disease)
- Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
- Gout flares (episodes of pain or swelling associated with a type of joint condition)

(Initial denial text continued on next page)

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CANAKINUMAB

INITIAL CRITERIA (CONTINUED)

If you have Cryopyrin-Associated Periodic Syndromes, including Familial Cold Auto-inflammatory Syndrome or Muckle-Wells Syndrome, approval also requires:
- You are 4 years of age or older
- You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
- You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Arcalyst [rilonacept]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Cryopyrin-Associated Periodic Syndromes, including Familial Cold Auto-inflammatory Syndrome or Muckle-Wells Syndrome (types of immune disorders)

If you have Tumor Necrosis Factor Receptor Associated Periodic Syndrome, approval also requires:
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (a type of genetic disease)

If you have Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency, approval also requires:
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency (types of genetic disorders)

If you have Familial Mediterranean Fever, approval also requires:
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Familial Mediterranean Fever (a type of genetic disorder)

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CANAKINUMAB

INITIAL CRITERIA (CONTINUED)

If you have Adult-Onset Still's Disease, approval also requires:
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Kineret [anakinra]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Adult-Onset Still's Disease (an autoinflammatory disease)
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kineret (anakinra)

If you have systemic juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Tyenne (tocilizumab-aazg)

If you have gout flares, approval also requires:
- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of gout flares (episodes of pain or swelling associated with a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) ALL of the following:
  - Colchicine
  - An NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, indomethacin)
  - A corticosteroid (such as triamcinolone, methylprednisolone, prednisone, prednisolone)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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CANAKINUMAB

RENEWAL CRITERIA

NOTE: For the diagnoses of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), or Familial Mediterranean Fever (FMF), please refer to the Initial Criteria section.

Does the patient have a diagnosis of Adult-Onset Still's Disease (AOSD) (ICD-10 M06.1) and meet **ALL** of the following criteria?

Ilaris will NOT be used concurrently with another systemic biologic (e.g., Kineret [anakinra]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of AOSD

The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis) or the patient has achieved a reduction in corticosteroid (e.g., prednisone) dose

The patient's disease is still clinically active (remission has not been attained) OR discontinuing therapy will result in harm to the patient

The patient had a trial of or contraindication to the preferred agent: Kineret (anakinra) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, continue to #2.

Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?

Ilaris will NOT be used concurrently with another systemic biologic (e.g., Actemra [tocilizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

The patient had a trial of or contraindication to the following preferred agent: Tyenne (tocilizumab-aazg)
[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify.]

If yes, continue to #3.
If no, continue to #4.

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CANAKINUMAB

RENEWAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient have a diagnosis of gout flares (ICD-10 Group M10) and meet **ALL** of the following criteria?
- The patient has shown improvement of gout flares while on Ilaris
- Therapy is prescribed by or in consultation with a rheumatologist
- Ilaris will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of gout flares

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Adult-Onset Still's Disease (AOSD: an autoinflammatory disease)
- Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
- Gout flares (episodes of pain or swelling associated with a type of joint condition)

(Renewal denial text continued on next page)

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CANAKINUMAB

RENEWAL CRITERIA (CONTINUED)

If you have Adult-Onset Still's Disease, renewal also requires:
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Kineret [anakinra]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Adult-Onset Still's Disease (an autoinflammatory disease)
- You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis [a type of joint condition]) or you have achieved a reduction (decrease) in your corticosteroid (such as prednisone) dose
- Your disease is still clinically active (remission [reduction or disappearance of the signs and symptoms of a disease] has not been attained) OR discontinuing therapy will be harmful for you
- You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kineret (anakinra)

If you have systemic juvenile idiopathic arthritis, renewal also requires:
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Tyenne (tocilizumab-aazg)
- You meet ONE of the following:
  - You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
  - You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis [a type of joint condition])

If you have gout flares, renewal also requires:
- You have shown improvement of gout flares while on Ilaris
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Ilaris concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of gout flares (episodes of pain or swelling associated with a type of joint condition)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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CANAKINUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ilaris.

REFERENCES

Ilaris [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; November 2024.

Created: 08/13
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CANTHARIDIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CANTHARIDIN	YCANTH	02578		GPI-10 (9075001000)	BRAND = YCANTH

GUIDELINES FOR USE

Does the plan benefit include non-self-administered (NSA) medications?

If yes, continue to #2.
If no, guideline does not apply.

Does the patient have a diagnosis of molluscum contagiosum (ICD-10 B08.1) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
Ycanth will NOT be used concurrently with another topical agent for the treatment of molluscum contagiosum (e.g., Zelsuvmi [berdazimer], Condylox [podofilox])
The patient had a trial of or contraindication to podofilox 0.5% topical solution

If yes, **approve for 12 weeks by HICL or GPI-10 with a quantity limit of #2 per 21 days.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CANTHARIDIN (Ycanth)** requires the following rule(s) be met for approval:
You have molluscum contagiosum (a viral skin infection)
You are 2 years of age or older
You will NOT use Ycanth concurrently (at the same time) with another topical medication for the treatment of molluscum contagiosum (a viral skin infection) (such as Zelsuvmi [berdazimer], Condylox [podofilox])
You have tried or have a contraindication to (harmful for you to use) podofilox 0.5% topical solution

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ycanth.

REFERENCES

Ycanth [Prescribing Information]. West Chester, PA: Verrica Pharmaceuticals Inc.; October 2024.

Created: 10/23
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPECITABINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPECITABINE	XELODA, CAPECITABINE	18385		GPI-10 (2130000500)	

GUIDELINES FOR USE

Does the patient have a diagnosis of Stage III colon cancer (ICD-10 Group C18) **AND** meet the following criterion?
The requested medication will be used as adjuvant treatment

If yes, **approve for 12 months by HICL or GPI-10 for 8 fills.**
If no, continue to #2.

Does the patient have a diagnosis of locally advanced rectal cancer (ICD-10 C20) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The requested medication will be used as perioperative treatment
The requested medication will be used as part of chemoradiotherapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Does the patient have a diagnosis of unresectable or metastatic colorectal cancer (ICD-10 C19)?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 C79.81, Group C50) and meet **ONE** of the following criteria?
The requested medication will be used as a single agent if an anthracycline- or taxane-containing chemotherapy is not indicated
The requested medication will be used in combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #5.

Does the patient have a diagnosis of unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer (ICD-10 Groups C15, C16) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The requested medication will be used as part of a combination chemotherapy regimen

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #6.

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has not received prior treatment for metastatic disease
The requested medication will be used as part of a combination regimen

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

Does the patient have a diagnosis of pancreatic adenocarcinoma (ICD-10 Group C25) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The requested medication will be used as adjuvant treatment
The requested medication will be used as part of a combination chemotherapy regimen

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CAPECITABINE (Xeloda)** requires the following rule(s) to be met for approval:
You have ONE of the following:
- Stage III colon cancer (the cancer that has spread to lymph nodes)
- Locally advanced rectal cancer (cancer that has spread from where it started to nearby tissue or lymph nodes)
- Unresectable (unable to remove by surgery) or metastatic colorectal cancer (a type of digestive cancer that has spread to other parts of the body)
- Metastatic breast cancer (the cancer that has spread to other parts of the body)
- Unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer (a type of digestive system cancer that has spread to other parts of the body)
- HER2 (a type of protein)-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)
- Pancreatic adenocarcinoma (a type of cancer of the pancreas)

If you have Stage III colon cancer, approval also requires:
The requested medication will be used as adjuvant (add-on) treatment
(Denial text continued on next page)

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CAPECITABINE

GUIDELINES FOR USE (CONTINUED)

If you have locally advanced rectal cancer, approval also requires:
- You are 18 years of age or older
- The requested medication will be used as perioperative (the time before and after surgery) treatment
- The requested medication will be used as part of chemoradiotherapy (a type of cancer treatment)

If you have advanced or metastatic breast cancer, approval also requires ONE of the following:
- The requested medication will be used as a single agent (used alone) if an anthracycline (such as doxorubicin, daunorubicin)- or taxane (such as paclitaxel, docetaxel)-containing chemotherapy is not indicated
- The requested medication will be used in combination with docetaxel after disease progression (worsens) on prior anthracycline (such as doxorubicin, daunorubicin)-containing chemotherapy

If you have unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer, approval also requires:
- You are 18 years of age or older
- The requested medication will be used as part of a combination chemotherapy (drugs used to treat cancer) regimen

If you have HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
- You are 18 years of age or older
- You have not received prior treatment for metastatic disease
- The requested medication will be used as part of a combination regimen (such as with cisplatin, trastuzumab)

If you have pancreatic adenocarcinoma, approval also requires:
- You are 18 years of age or older
- The requested medication will be used as adjuvant (add-on) treatment
- The requested medication will be used as part of a combination chemotherapy regimen (such as with gemcitabine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CAPECITABINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeloda.

REFERENCES

Xeloda [Prescribing Information]. South San Francisco, CA: Genentech Inc., December 2022.

Created: 02/13
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPIVASERTIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPIVASERTIB	TRUQAP	49313		GPI-10 (2153032000)	

GUIDELINES FOR USE

Does the patient have a diagnosis of locally advanced or metastatic breast cancer (ICD-10 C79.81, Group C50) and meet **ALL** of the following criteria?
Truqap will be used in combination with Faslodex (fulvestrant)
The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, with one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test
The patient has disease progression on or after an endocrine-based regimen (e.g., letrozole, anastrozole, tamoxifen)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #64 per 28 days.**
If no, continue to #2.

Does the patient have a diagnosis of metastatic androgen pathway modulation-naive or -sensitive (mAPMN/S) prostate cancer (ICD-10 C61, Z19.1) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Truqap will be used in combination with abiraterone (Zytiga) and prednisone
The cancer is PTEN-deficient as detected by an FDA-authorized test

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #64 per 28 days.**
If no, continue to #3.

Is the request for a currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document? (see FDA website for approved drugs indications: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #64 per 28 days.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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CAPIVASERTIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline named **CAPIVASERTIB (Truqap)** requires the following rule(s) be met for approval:

You have ONE of the following:

- Locally advanced or metastatic breast cancer (breast cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
- Metastatic androgen pathway modulation-naive or -sensitive (mAPMN/S) prostate cancer (cancer that has spread to other parts of the body and has not been treated with, or may respond to, testosterone-lowering treatment)
- A currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document

If you have locally advanced or metastatic breast cancer, approval also requires:

- Truqap will be used together with Faslodex (fulvestrant)
- Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, with one or more PIK3CA/AKT1/PTEN-mutations (abnormal changes in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test
- You have experienced disease progression (worsening) on or after an endocrine (hormone)-based regimen (such as letrozole, anastrozole, tamoxifen)

If you have metastatic androgen pathway modulation-naive or -sensitive prostate cancer, approval also requires:

- You are 18 years of age or older
- Truqap will be used in combination with abiraterone (Zytiga) and prednisone
- Your prostate cancer is PTEN-deficient (loss of a type of gene) as detected by a Food and Drug Administration (FDA)-authorized test

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Truqap.

REFERENCES

Truqap [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2026.

Created: 11/23
Effective: 07/08/26 Client Approval: 07/26 DMC Approval: 06/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPLACIZUMAB-YHDP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPLACIZUMAB-YHDP	CABLIVI	45591		GPI-10 (8515102080)	

GUIDELINES FOR USE

Does the patient have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP) (ICD- 10 Group M31.1) and meet **ALL** of the following criteria?
The patient is 12 years of age or older
Therapy is prescribed by or in consultation with a hematologist

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Has the patient experienced more than TWO recurrences of aTTP while on Cablivi therapy (i.e., new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy [PEX] and up to 28 days of extended therapy)?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

Is the request for continuation of Cablivi therapy from an inpatient (hospital) setting **AND** the patient meets the following criterion?
Cablivi was previously initiated as part of an FDA-approved treatment regimen in combination with plasma exchange and immunosuppressive therapy within the inpatient setting

If yes, **approve for 1 month by HICL or GPI-10 for a maximum quantity of #30 vials.**
If no, continue to #4.

Is the request for continuation of Cablivi therapy after the initial 30-day treatment course (e.g., with no break in therapy) and the patient meets **ALL** of the following criteria?
The patient is receiving immunosuppressive therapy
The patient is experiencing signs of persistent underlying disease (e.g., suppressed ADAMTS13 [also known as von Willebrand factor-cleaving protease (VWFCP)] activity level remains present)

If yes, **approve for 1 month by HICL or GPI-10 for a maximum quantity of #28 vials.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPLACIZUMAB-YHDP

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CAPLACIZUMAB-YHDP (Cablivi)** requires the following rule(s) be met for approval:
You have acquired thrombotic thrombocytopenia purpura (aTTP: a type of blood disorder)
You are 12 years of age or older
Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
You have NOT experienced more than TWO recurrences of acquired thrombotic thrombocytopenia purpura (aTTP: a type of blood disorder) while on Cablivi therapy. Recurrences include a new drop in platelet (type of blood cell) count requiring repeat plasma exchange during 30 days post-plasma exchange therapy (PEX: filtering of blood) and up to 28 days of extended therapy
You also meet ONE of the following:
- Your request is for continuation of Cablivi therapy from an inpatient (hospital) setting, AND Cablivi was previously initiated as part of a Food and Drug Administration (FDA)-approved treatment regimen in combination with plasma exchange (filtering of blood) and immunosuppressive therapy (treatment that weakens the immune system) within the inpatient setting
- Your request is for continuation of Cablivi therapy after the initial 30-day treatment course (with no break in therapy) and you meet ALL of the following:
  - You are receiving immunosuppressive therapy
  - You are experiencing signs of persistent underlying disease (such as suppressed ADAMTS13 [also known as von Willebrand factor-cleaving protease (VWFCP): a type of enzyme] activity level remains present)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cablivi.

REFERENCES

Cablivi [Prescribing Information]. Cambridge, MA: Genzyme Corporation; December 2025.

Created: 05/19
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 04/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CAPMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPMATINIB HYDROCHLORIDE	TABRECTA	46519		GPI-10 (2153371620)	

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's tumor has a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CAPMATINIB (Tabrecta)** requires the following rule(s) be met for approval:
You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
You are 18 years of age or older
Your tumor has a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping (an abnormal change in a gene that makes MET protein) as detected by a Food and Drug Administration (FDA)-approved test

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tabrecta.

REFERENCES

Tabrecta [Prescribing Information]. East Hanover, NJ: Novartis; March 2024.

Created: 08/20
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CARBIDOPA-LEVODOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARBIDOPA/ LEVODOPA	DUOPA		37829	GPI-14 (73209902101820)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of advanced Parkinson's disease (ICD-10 Group G20) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a neurologist
- The patient is experiencing at least 3 hours of “off” time on current Parkinson’s disease drug treatment
- The patient has demonstrated a clear responsiveness to treatment with levodopa

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ONE** of the following criteria?
- The patient is unable to swallow extended-release tablets or administer extended-release capsules via feeding tube
- The patient has failed to adhere to an oral carbidopa/levodopa regimen or tolerate a feeding tube carbidopa/levodopa regimen

If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #100mL per day.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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CARBIDOPA-LEVODOPA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CARBIDOPA-LEVODOPA (Duopa)** requires the following rule be met for approval:
You have advanced Parkinson's disease (a type of movement disorder)
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
You are experiencing at least 3 hours of “off” time (period of symptoms in between doses) on your current Parkinson’s disease drug treatment (medication for a type of movement disorder)
You have shown a clear responsiveness to treatment with levodopa
You meet ONE of the following:
- You are unable to swallow extended-release tablets or administer extended-release capsules through a feeding tube
- You have failed to adhere to (keep up with) an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen through a feeding tube

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CARBIDOPA-LEVODOPA

RENEWAL CRITERIA

Does the patient have a diagnosis of advanced Parkinson's disease (ICD-10 Group G20) **AND** meet the following criterion?
The patient has experienced improvement in motor symptoms

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #100mL per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CARBIDOPA-LEVODOPA (Duopa)** requires the following rule(s) be met for renewal:
You have advanced Parkinson's disease (a type of movement disorder)
You have experienced improvement in motor symptoms (ability to move)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Duopa.

REFERENCES

Duopa [Prescribing Information]. North Chicago, IL: Abbvie, Inc.; March 2022.

Created: 05/15
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CARBOXYMETHYLCELLULOSE-CITRIC

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARBOXYMETHYLCELLULOSE /CITRIC	PLENITY	47522		GPI-10 (6120990202)	

GUIDELINES FOR USE

Is the request for weight management (ICD-10 Group E66) and the patient meets **ALL** of the following criteria?
The patient is 18 years of age or older
The patient has a body mass index (BMI) of 25 to 40 kg/m(2)
Plenity will be used in conjunction with diet and exercise

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #168 per 28 days.** If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CARBOXYMETHYLCELLULOSE-CITRIC (Plenity)** requires the following rule(s) be met for approval:
The request is for weight management
You are 18 years of age or older
You have a body mass index (BMI) of 25 to 40 kg/m(2)
Plenity will be used in conjunction (together) with diet and exercise

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Plenity.

REFERENCES

Plenity [Prescribing Information]. Boston, MA: Gelesis, Inc., 2019.

Created: 08/21
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/21

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CARFILZOMIB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARFILZOMIB	KYPROLIS	39338		GPI-10 (2153602500)	

GUIDELINES FOR USE

Does the patient have a diagnosis of relapsed or refractory multiple myeloma (MM) **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Has the patient previously received one or more lines of therapy **AND** Kyprolis will be used as a single agent?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Has the patient previously received one to three lines of therapy **AND** Kyprolis will be used in combination with ONE of the following regimens?
Lenalidomide and dexamethasone
Dexamethasone
Daratumumab and dexamethasone
Daratumumab-hyaluronidase-fihj and dexamethasone
Isatuximab and dexamethasone

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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CARFILZOMIB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CARFILZOMIB (Kyprolis)** requires the following rule(s) be met for approval:

You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment)
You are 18 years of age or older
You meet ONE of the following:
- You have previously received one or more lines of multiple myeloma therapy AND will be using Kyprolis alone
- You have previously received one to three lines of therapy AND will be using Kyprolis in combination with ONE of the following:
  - Lenalidomide and dexamethasone
  - Dexamethasone
  - Daratumumab and dexamethasone
  - Daratumumab-hyaluronidase-fihj and dexamethasone
  - Isatuximab and dexamethasone

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kyprolis.

REFERENCES

Kyprolis [Prescribing Information]. Thousand Oaks, CA: Onyx Pharmaceuticals; June 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 05/01/23
Created: 11/12
Client Approval: 04/23
P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CARGLUMIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CARGLUMIC ACID	CARBAGLU CARGLUMIC ACID	25643		GPI-10 (3090823000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of acute or chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (ICD-10 E72.29) **AND** meet the following criterion?
The patient's NAGS gene mutation is confirmed by biochemical or genetic testing

If yes, **approve by HICL or GPI-10 as follows:**
Acute HA due to NAGS deficiency: approve for 7 days.
Chronic HA due to NAGS deficiency: approve for 6 months.

If no, continue to #2.

Does the patient have a diagnosis of acute hyperammonemia (HA) due to propionic acidemia (PA) (ICD-10 E71.121) as confirmed by **ONE** of the following criteria?
The patient has elevated methylcitric acid AND normal methylmalonic acid
The patient had genetic testing confirming mutation in the PCCA or PCCB gene

If yes, **approve for 7 days by HICL or GPI-10.**
If no, continue to #3.

Does the patient have a diagnosis of acute hyperammonemia (HA) due to methylmalonic acidemia (MMA) (ICD-10 E71.120) as confirmed by **ONE** of the following criteria?
The patient has elevated methylmalonic acid and methylcitric acid
The patient had genetic testing confirming mutation in the MMUT, MMA, MMAB or MMADHC genes

If yes, **approve for 7 days by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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CARGLUMIC ACID

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CARGLUMIC ACID (Carbaglu)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Acute or chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (short-term or long-term high ammonia blood levels due to a genetic disorder)
- Acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (short-term high ammonia blood levels due to a genetic disorder)

If you have acute or chronic hyperammonemia due to N-acetylglutamate synthase deficiency, approval also requires:
- Your N-acetylglutamate synthase gene mutation (abnormal change in gene) is confirmed by biochemical or genetic testing (types of lab tests)

If you have acute hyperammonemia due to propionic acidemia, approval also requires your diagnosis is confirmed by ONE of the following:
- You have elevated methylcitric acid AND normal methylmalonic acid (substances that indicate presence of a disease)
- You had genetic testing confirming mutation in the PCCA or PCCB gene (abnormal changes in types of genes)

If you have acute hyperammonemia due to methylmalonic acidemia, approval also requires your diagnosis is confirmed by ONE of the following:
- You have elevated methylmalonic acid and methylcitric acid (substances that indicate presence of a disease)
- You had genetic testing confirming mutation in the MMUT, MMA, MMAB or MMADHC genes (abnormal changes in types of genes)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CARGLUMIC ACID

RENEWAL CRITERIA

NOTE: For the diagnoses of acute hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency or acute hyperammonemia (HA) due to propionic acidemia (PA) or methylmalonic acidemia (MMA), please refer to the Initial Criteria section.

Does the patient have a diagnosis of chronic hyperammonemia (HA) due to N- acetylglutamate synthase (NAGS) deficiency (ICD-10 E72.29) **AND** meet the following criterion?
The patient has clinical improvement or improved plasma (blood) ammonia levels

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CARGLUMIC ACID (Carbaglu)** requires the following rule(s) be met for renewal:
You have chronic hyperammonemia (HA) due to N-acetylglutamate synthase (NAGS) deficiency (long-term high ammonia blood levels due to a genetic disorder)
You have clinical improvement or improved plasma (blood) ammonia levels

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Carbaglu.

REFERENCES

Carbaglu [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; January 2024.

Created: 05/22
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CASIMERSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CASIMERSEN	AMONDYS-45	47149		GPI-10 (7460002500)	

GUIDELINES FOR USE

Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) **AND** meet the following criterion?
The patient has a confirmed mutation in the DMD gene that is amenable to exon 45 skipping

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CASIMERSEN (Amondys-45)** requires the following rule(s) be met for approval:
You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
You have a confirmed mutation in the DMD gene that is responsive to exon 45 skipping (a type of gene mutation)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Amondys-45.

REFERENCES

Amondys-45 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc.; July 2024.

Created: 05/21
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CELECOXIB - ELYXYB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CELECOXIB	ELYXYB		48006	GPI-10 (6760403000)	

GUIDELINES FOR USE

Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
The patient is 18 years of age or older
The patient is unable to swallow pills (e.g., tablets or capsules)
The patient had a trial of or contraindication to the preferred agent: generic ibuprofen oral liquid formulation

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #38.4mL per 30 days.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CELECOXIB - ELYXYB** requires the following rule(s) be met for approval:
The request is for the acute (quick onset) treatment of migraines (type of headache)
You are 18 years of age or older
You are unable to swallow pills (such as tablets or capsules)
You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic ibuprofen oral liquid formulation

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elyxyb.

REFERENCES

Elyxyb [Prescribing Information]. Palo Alto, CA: SCILEX Pharmaceuticals Inc.; November 2024.

Created: 02/22
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CELECOXIB-VYSCOXA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CELECOXIB	VYSCOXA		58139	GPI-14 (66100525001820)	

GUIDELINES FOR USE

Does the patient have a diagnosis of osteoarthritis (OA) (ICD-10 Groups M15, M16, M17, M18, M19, M47) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has a contraindication to or is unable to swallow celecoxib capsules
- The patient had a trial of or contraindication to the preferred agent: generic ibuprofen oral liquid formulation

If yes, **approve for 12 months by GPID or GPI-14.**
If no, continue to #2.

Does the patient have a diagnosis of rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has a contraindication to or is unable to swallow celecoxib capsules
- The patient had a trial of or contraindication to the preferred agent: generic ibuprofen oral liquid formulation

If yes, **approve for 12 months by GPID or GPI-14.**
If no, continue to #3.

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has a contraindication to or is unable to swallow celecoxib capsules
- The patient had a trial of or contraindication to the preferred agent: generic ibuprofen oral liquid formulation

If yes, **approve for 12 months by GPID or GPI-14.**
If no, continue to #4.

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CELECOXIB-VYSCOXA

GUIDELINES FOR USE (CONTINUED)

Does the patient have a diagnosis of juvenile rheumatoid arthritis (JRA) (ICD-10 M08.3; Group M08.0) and meet **ALL** of the following criteria?
The patient is 2 years of age or older
The patient has a contraindication to or is unable to swallow celecoxib capsules
The patient had a trial of or contraindication to the preferred agent: generic ibuprofen oral liquid formulation

If yes, **approve for 12 months by GPID or GPI-14.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CELECOXIB-VYSCOXA** requires the following rule(s) be met for approval:
You have ONE of the following:
Osteoarthritis (OA: type of joint condition)
Rheumatoid arthritis (RA: type of joint condition)
Ankylosing spondylitis (AS: type of joint condition)
Juvenile rheumatoid arthritis (JRA: type of joint condition)
If you have osteoarthritis, approval also requires:
You are 18 years of age or older
You have a contraindication to (harmful for you to use) or are unable to swallow celecoxib capsules
You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic ibuprofen oral liquid formulation
If you have rheumatoid arthritis, approval also requires:
You are 18 years of age or older
You have a contraindication to (harmful for you to use) or are unable to swallow celecoxib capsules
You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic ibuprofen oral liquid formulation
If you have ankylosing spondylitis, approval also requires:
You are 18 years of age or older
You have a contraindication to (harmful for you to use) or are unable to swallow celecoxib capsules
You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic ibuprofen oral liquid formulation
(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

If you have juvenile rheumatoid arthritis, approval also requires:

You are 2 years of age or older

You have a contraindication to (harmful for you to use) or are unable to swallow celecoxib capsules

You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic ibuprofen oral liquid formulation

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyscoxa.

REFERENCES

Vyscoxa [Prescribing Information]. Hazlet, NJ: Carwin Pharmaceutical Associates, LLC; July 2025.

Created: 10/25
Effective: 11/10/25 Client Approval: 10/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CEMIPLIMAB-RWLC

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CEMIPLIMAB-RWLC	LIBTAYO	45284		GPI-10 (2135792340)	

GUIDELINES FOR USE

Does the patient have a diagnosis of cutaneous squamous cell carcinoma (CSCC) (ICD-10 C44.02, C44.82, C44.92; Groups C44.12, C44.22, C44.32, C44.42, C44.52, C44.62, C44.72) and meet **ONE** of the following criteria?
The patient's cancer is metastatic or locally advanced AND the patient is not a candidate for curative surgery or curative radiation
The patient's cancer is at high risk of recurrence after surgery and radiation AND Libtayo will be used as adjuvant treatment

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #2.

Does the patient have a diagnosis of metastatic or locally advanced basal cell carcinoma (BCC) (ICD-10 C44.91, C44.01, C44.41, C44.81; Groups C44.11, C44.21, C44.31, C44.51, C44.61, C44.71) **AND** meet the following criterion?
The patient has previously been treated with a hedgehog pathway inhibitor (e.g., Erivedge [vismodegib], Odomzo [sonidegib]) or for whom a hedgehog pathway inhibitor is not appropriate

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's cancer is metastatic OR locally advanced (where the patient is not a candidate for surgical resection or definitive chemoradiation)
The patient's tumors do not have EGFR, ALK, or ROS1 aberrations

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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CEMIPLIMAB-RWLC

GUIDELINES FOR USE (CONTINUED)

Does the patient meet **ONE** of the following criteria?

- Libtayo will be used as a single agent AND the patient's tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%], as determined by an FDA-approved test
- Libtayo will be used in combination with platinum-based chemotherapy (e.g., carboplatin, cisplatin)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CEMIPLIMAB-RWLC (Libtayo)** requires the following rules be met for approval:
You have ONE of the following diagnoses:

- Cutaneous squamous cell carcinoma (a type of skin cancer)
- Metastatic or locally advanced basal cell carcinoma (a type of skin cancer that has spread to other parts of the body or to nearby tissue or lymph nodes)
- Non-small cell lung cancer (a type of lung cancer)

If you have cutaneous squamous cell carcinoma, approval also requires ONE of the following:

- Your cancer is metastatic or locally advanced (cancer that has spread to other parts of the body or to nearby tissue or lymph nodes) AND you are not a candidate for curative (to cure) surgery or curative radiation
- Your cancer is at high risk of recurrence (returning) after surgery and radiation AND Libtayo will be used as adjuvant (additional) treatment

If you have metastatic or locally advanced basal cell carcinoma, approval also requires:

- You have previously been treated with a hedgehog pathway inhibitor (such as Erivedge [vismodegib], Odomzo [sonidegib]) or a hedgehog pathway inhibitor is not appropriate for you

(Denial text continued on next page)

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CEMIPLIMAB-RWLC

GUIDELINES FOR USE (CONTINUED)

If you have non-small cell lung cancer, approval also requires:

- You are 18 years of age or older
- Your cancer is metastatic (cancer that has spread to other parts of the body) OR locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes, where you are not a candidate for surgical resection [remove by surgery] or definitive chemoradiation [a type of cancer treatment])
- Your tumors do not have EGFR, ALK or ROS1 aberrations (types of abnormal genes)
- You meet ONE of the following:
  - Libtayo will be used as a single agent AND your tumors has high PD-L1 (programmed death-ligand: type of protein) expression [Tumor Proportion Score (TPS) at least 50%], as determined by a Food and Drug Administration (FDA)- approved test
  - Libtayo will be used in combination with platinum-based chemotherapy (such as carboplatin, cisplatin)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Libtayo.

REFERENCES

Libtayo [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2025.

Created: 11/18
Effective: 11/01/25 Client Approval: 10/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CENEGERMIN-BKBJ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CENEGERMIN-BKBJ	OXERVATE	45258		GPI-10 (8677002020)	

GUIDELINES FOR USE

Does the patient have a diagnosis of neurotrophic keratitis (NK) (ICD-10 Group H16.23) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient has a medical history supportive of causative etiology for trigeminal nerve damage (e.g., herpes zoster infection, multiple sclerosis, diabetes, ocular surgical damage)
- The patient has loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
- The patient is refractory to conservative management (i.e., artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Has the patient previously completed an 8-week course of Oxervate (cenegermin-bkbj) in the affected eye(s) during their lifetime?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #28 vials per 14 days for 4 fills.**

DENIAL TEXT: Our guideline named **CENEGERMIN-BKBJ (Oxervate)** requires the following rule(s) be met for approval:
- You have neurotrophic keratitis (an eye disease due to a damaged eye nerve)
- Therapy is prescribed by or in consultation with an ophthalmologist (eye doctor)
- You have a medical history that supports a cause for trigeminal nerve damage (damage to a nerve in the head) (such as herpes zoster infection [shingles virus], multiple sclerosis [type of nerve disorder], diabetes (a disorder with high blood sugar), ocular surgical [eye surgery] damage)
- You have loss of corneal (a part of the eye) sensitivity, corneal epithelium changes, and/or loss of tear production
- You are refractory (not fully responsive) to conservative management (artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses)
- You have NOT previously completed an 8-week course of Oxervate (cenegermin-bkbj) in the affected eye(s) during your lifetime

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CENEGERMIN-BKBJ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oxervate.

REFERENCES

Oxervate [Prescribing Information]. Boston, MA: Dompe U.S., Inc.; February 2025.

Created: 02/19
Effective: 07/29/26 Client Approval: 07/26 P&T Approval: 01/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERITINIB	ZYKADIA	41111		GPI-10 (2153051400)	

GUIDELINES FOR USE

Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
The patient's tumor is anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CERITINIB (Zykadia)** requires the following rule(s) be met for approval:
You have metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
You are 18 years of age or older
Your tumor is anaplastic lymphoma kinase (ALK)-positive (a type of defect in a gene) as confirmed by a Food and Drug Administration (FDA)-approved test

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zykadia.

REFERENCE

Zykadia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2021.

Created: 05/14
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 10/21

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERLIPONASE ALFA (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERLIPONASE ALFA	BRINEURA	44258		GPI-10 (3090902010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2 disease) (ICD-10 E75.4), also known as tripeptidyl peptidase 1 (TPP1) deficiency, and meet **ALL** of the following criteria?

Therapy is prescribed by or in consultation with a neurologist or pediatric CLN2 specialist
The patient's diagnosis is confirmed by TPP1 enzyme deficiency test or TPP1/CLN2 genotyping
The patient is ambulatory and experiencing symptoms (e.g., instability, intermittent falls, requires assistance to walk, can crawl only)
The patient has a CLN2 Clinical Rating Scale Score of 3 to 5, with a minimum score of 1 in each of the motor and language domains

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 kits per 28 days.** If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CERLIPONASE ALFA (Brineura)** requires the following rule(s) be met for approval:

You have neuronal ceroid lipofuscinosis type 2 (CLN2 disease: a type of genetic disorder), also known as tripeptidyl peptidase 1 (TPP1) deficiency (a type of genetic disorder)
Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or pediatric (children) CLN2 specialist
Your diagnosis is confirmed by TPP1 enzyme deficiency test or TPP1/CLN2 genotyping (types of lab test)
You are ambulatory (able to walk or crawl) and experiencing symptoms (such as instability [not able to control movement], intermittent (on-and-off) falls, needs help to walk, can crawl only)
You have a CLN2 Clinical Rating Scale Score (a test to measure the severity of ceroid lipofuscinosis type 2) of 3 to 5, with a minimum score of 1 in each of the motor and language category

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERLIPONASE ALFA (NSA)

RENEWAL CRITERIA

Does the patient meet **ALL** of the following criteria?

The patient has improved or maintained baseline motor function (e.g., ambulation, walking, crawling), or demonstrated a less-than-expected decline in motor function (e.g., ambulation, walking or crawling) from baseline

The patient has a ceroid lipofuscinosis type 2 (CLN2) motor score of at least 1 (e.g., patient is not bedridden or immobile)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 kits per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CERLIPONASE ALFA (Brineura)** requires the following rule(s) be met for renewal:

You have improved or maintained baseline (before starting Brineura) motor function (such as ambulation [ability to move], walking, crawling) or demonstrated a less-than-expected decline in motor function (such as ambulation, walking or crawling) from baseline

You have a ceroid lipofuscinosis type 2 (CLN2) motor score (a score to assess severity of symptoms) of at least 1 (such as you are not bedridden [not able to get out of bed] or immobile [not able to move])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brineura.

REFERENCES

Brineura [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical Inc.; July 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 08/19/24
Created: 08/17
Client Approval: 08/24
P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CERTOLIZUMAB PEGOL	CIMZIA	35554		GPI-10 (5250502010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
The patient is 18 years of age or older
Therapy is prescribed by or in consultation with a rheumatologist
Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

If yes, continue to #2.
If no, continue to #3.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
- The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #3 kits per 28 days.)**

  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

  If yes, continue to #4.
  If no, continue to #5.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #3 kits per 28 days.)**

  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

  If yes, continue to #6.
  If no, continue to #7.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #3 kits per 28 days.)**

  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
- The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)

  If yes, continue to #8.
  If no, continue to #9.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #3 kits per 28 days.)**

  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
- The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)

  If yes, continue to #10.
  If no, continue to #11.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient was previously stable on another biologic and is switching to Cimzia
- The patient has C-reactive protein (CRP) levels above the upper limit of normal
- The patient has sacroiliitis on magnetic resonance imaging (MRI)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #3 kits per 28 days.)**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, face, or scalp
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

If yes, continue to #12.
If no, continue to #14.

Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant and PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

If yes, continue to #13.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Taltz (ixekizumab)
  - Sotyktu (deucravacitinib)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Icotyde (icotrokinra)
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 kits per 28 days.**

  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

  If yes, continue to #15.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to ONE of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Skyrizi (risankizumab-rzaa)
  - Tremfya (guselkumab)
  - Omvoh (mirikizumab-mrkz)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #3 kits per 28 days.)**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe rheumatoid arthritis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
- You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Enbrel (etanercept)
    - Adalimumab-ryvk/adalimumab-aaty
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

If you have polyarticular juvenile idiopathic arthritis, approval also requires:
- You are 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Enbrel (etanercept)
    - Adalimumab-ryvk/adalimumab-aaty
    - Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Enbrel (etanercept)
    - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    - Otezla (apremilast)
    - Tremfya (guselkumab)
    - Skyrizi (risankizumab-rzaa)
    - Taltz (ixekizumab)
    - Bimzelx (bimekizumab-bkzx)
    - Sotyktu (deucravacitinib)
    - Adalimumab-ryvk/adalimumab-aaty
    - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Enbrel (etanercept)
    - Taltz (ixekizumab)
    - Bimzelx (bimekizumab-bkzx)
    - Adalimumab-ryvk/adalimumab-aaty
    - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

If you have non-radiographic axial spondyloarthritis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)
- You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
- You meet ONE of the following:
  - You were previously stable on another biologic and are switching to Cimzia
  - You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
  - You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
- You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
- You meet ONE of the following:
  - You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
  - You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
  - You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor) for the same indication
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    - Tremfya (guselkumab)
    - Skyrizi (risankizumab-rzaa)
    - Enbrel (etanercept)
    - Otezla (apremilast)
    - Taltz (ixekizumab)
    - Sotyktu (deucravacitinib)
    - Bimzelx (bimekizumab-bkzx)
    - Adalimumab-ryvk/adalimumab-aaty
    - Icotyde (icotrokinra)

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CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, approval also requires:

- You are 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
    - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    - Skyrizi (risankizumab-rzaa)
    - Tremfya (guselkumab)
    - Omvoh (mirikizumab-mrkz)
    - Adalimumab-ryvk/adalimumab-aaty
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA

Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

If yes, continue to #2.
If no, continue to #3.

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
- The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA

If yes, continue to #4.
If no, continue to #5.

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, continue to #6.
If no, continue to #7.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**

  If no, do not approve.
  DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

  If yes, continue to #8.
  If no, continue to #9.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**

  If no, do not approve.
  DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
- The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA

  If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.**
  If no, continue to #10.

Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

  If yes, continue to #11.
  If no, continue to #12.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Taltz (ixekizumab)
  - Sotyktu (deucravacitinib)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Icotyde (icotrokinra)
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 kits per 28 days.**

  If no, do not approve.
  DENIAL TEXT: See the renewal denial text at the end of the guideline.

Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50)
- **AND** meet the following criterion?
- Cimzia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

  If yes, continue to #13.
  If no, do not approve.
  DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

Does the patient meet **ONE** of the following criteria?
- The patient is pregnant, breastfeeding, or trying to become pregnant
- The patient had a trial of or contraindication to ONE of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Skyrizi (risankizumab-rzaa)
  - Tremfya (guselkumab)
  - Omvoh (mirikizumab-mrkz)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
  - [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 kit per 28 days.** If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
- Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
- Psoriatic arthritis (PsA: a type of skin and joint condition)
- Ankylosing spondylitis (AS: a type of joint condition)
- Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
- Moderate to severe plaque psoriasis (PsO: a type of skin condition)
- Moderate to severe Crohn's disease (CD: a type of bowel disorder)

If you have moderate to severe rheumatoid arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

You meet ONE of the following:
- You are pregnant, breastfeeding, or trying to become pregnant
- You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
- You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Enbrel (etanercept)
    - Adalimumab-ryvk/adalimumab-aaty
    - Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

If you have psoriatic arthritis, renewal also requires:

- You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Enbrel (etanercept)
    - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    - Otezla (apremilast)
    - Tremfya (guselkumab)
    - Skyrizi (risankizumab-rzaa)
    - Taltz (ixekizumab)
    - Bimzelx (bimekizumab-bkzx)
    - Sotyktu (deucravacitinib)
    - Adalimumab-ryvk/adalimumab-aaty
    - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

If you have ankylosing spondylitis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    - Enbrel (etanercept)
    - Taltz (ixekizumab)
    - Bimzelx (bimekizumab-bkzx)
    - Adalimumab-ryvk/adalimumab-aaty
    - Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

If you have non-radiographic axial spondyloarthritis, renewal also requires:
- You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe plaque psoriasis, renewal also requires:

You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy

You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

You meet ONE of the following:

You are pregnant, breastfeeding, or trying to become pregnant

You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:

Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
Tremfya (guselkumab)
Skyrizi (risankizumab-rzaa)
Enbrel (etanercept)
Otezla (apremilast)
Taltz (ixekizumab)
Sotyktu (deucravacitinib)
Bimzelx (bimekizumab-bkzx)
Adalimumab-ryvk/adalimumab-aaty
Icotyde (icotrokinra)

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CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

If you have moderate to severe Crohn's disease, renewal also requires:
- You will NOT use Cimzia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
- You meet ONE of the following:
  - You are pregnant, breastfeeding, or trying to become pregnant
  - You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
    - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    - Skyrizi (risankizumab-rzaa)
    - Tremfya (guselkumab)
    - Omvoh (mirikizumab-mrkz)
    - Adalimumab-ryvk/adalimumab-aaty
    - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Cimzia.

REFERENCES
Cimzia [Prescribing Information]. Smyrna, GA: UCB, Inc.; September 2025.

Created: 05/08
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CETUXIMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CETUXIMAB	ERBITUX	25947		GPI-10 (2136001500)	

GUIDELINES FOR USE

Does the patient have a diagnosis of locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
Erbitux will be used in combination with radiation therapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #2.

Does the patient have a diagnosis of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
Erbitux will be used in combination with platinum-based therapy (e.g., cisplatin, carboplatin, oxaliplatin) and 5-fluorouracil (5-FU)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
The patient has failed prior platinum-based therapy (e.g., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19)?

If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

Will Erbitux be used in combination with Krazati (adagrasib)?

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #6.

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CETUXIMAB

GUIDELINES FOR USE (CONTINUED)

Is the patient's cancer KRAS wild-type (without mutation), epidermal growth factor receptor (EGFR)-expressing, as determined by an FDA-approved test, and the patient meets **ONE** of the following criteria?
- Erbitux will be used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin)
- Erbitux will be used in combination with irinotecan AND the patient is refractory to irinotecan-based chemotherapy
- The patient has failed oxaliplatin-based and irinotecan-based chemotherapy OR the patient is intolerant to irinotecan

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #7.

Does the patient's cancer have a BRAF V600E mutation, as determined by an FDA-approved test, and the patient meets **ALL** of the following criteria?
- The patient is 18 years of age or older
- Erbitux will be used in combination with Braftovi (encorafenib) and fluorouracil-based chemotherapy (e.g., mFOLFOX6, FOLFIRI), OR Erbitux will be used in combination with Braftovi (encorafenib) after prior therapy (e.g., irinotecan)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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CETUXIMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CETUXIMAB (Erbitux)** requires the following rule(s) be met for approval:
You have ONE of the following:
- Locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN: a type of head and neck cancer that has spread from where it started to nearby tissue or lymph nodes)
- Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck (SCCHN: a type of head and neck cancer that has returned or has spread to other parts of the body)
- Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN: a type of head and neck cancer that has returned or has spread to other parts of the body)
- Metastatic colorectal cancer (mCRC: a type of digestive system cancer that has spread to other parts of the body)

If you have locally or regionally advanced squamous cell carcinoma of the head and neck, approval also requires:
Erbitux will be used in combination with radiation therapy

If you have recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, approval also requires:
Erbitux will be used in combination with platinum-based therapy (such as cisplatin, carboplatin, oxaliplatin) and 5-fluorouracil (5-FU)

If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:
You have previously failed platinum-based therapy (such as cisplatin, carboplatin, oxaliplatin)

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CETUXIMAB

GUIDELINES FOR USE (CONTINUED)

If you have metastatic colorectal cancer (mCRC), approval also requires ONE of the following:

Erbitux will be used in combination with Krazati (adagrasib)

Your cancer is KRAS wild-type (a type of gene with no mutation), epidermal growth factor receptor (EGFR)-expressing, as determined by a Food and Drug Administration (FDA)-approved test, AND you meet ONE of the following:

Erbitux will be used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin)

Erbitux will be used in combination with irinotecan and you are refractory (resistant) to irinotecan-based chemotherapy

You have failed oxaliplatin-based and irinotecan-based chemotherapy OR you are intolerant to irinotecan

Your cancer has a BRAF V600E mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test, and you meet ALL of the following:

You are 18 years of age or older

You meet ONE of the following:

Erbitux will be used in combination with Braftovi (encorafenib) and fluorouracil-based chemotherapy (such as mFOLFOX6 [fluorouracil, leucovorin and oxaliplatin], FOLFIRI [fluorouracil, leucovorin, and irinotecan])

Erbitux will be used in combination with Braftovi (encorafenib), and you have previously received treatment (such as irinotecan)

RATIONALE

For further information, please refer to the prescribing information and/or Drug Monograph for Erbitux.

REFERENCES

Erbitux [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2021.
Braftovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; February 2026.
Krazati [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2026.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHENODIOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CHENODIOL	CHENODAL, CTEXLI	01364		GPI-10 (5210001000, 5270002100)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of cerebrotendinous xanthomatosis (CTX) (ICD-10 E75.5)?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
If no, continue to #2.

Does the patient have a diagnosis of radiolucent gallstone(s) (ICD-10 Group K80.0) and meet **ALL** of the following criteria?
The patient had a trial of or contraindication to the clinical standard of care agent: ursodiol
The patient has NOT previously received a total duration of chenodiol therapy exceeding 24 months
The request is for Chenodal

If yes, **approve Chenodal for 12 months by NDC (FDB) or GPI-10 with a quantity limit of #7 per day.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHENODIOL (Chenodal, Ctexli)** requires the following rule(s) be met for approval:
You have ONE of the following:
Cerebrotendinous xanthomatosis (a type of genetic disorder)
Radiolucent gallstone(s) (hardened deposits of bile in the gall bladder that are barely seen on X-rays [a type of imaging test])
If you have radiolucent gallstone(s), approval also requires:
You have tried or have a contraindication to (harmful for you to use) the clinical standard of care agent: ursodiol
You have NOT previously received chenodiol therapy for more than a total of 24 months
Your request is for Chenodal

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CHENODIOL

RENEWAL CRITERIA

Does the patient have a diagnosis of cerebrotendinous xanthomatosis (CTX) (ICD-10 E75.5) and has experienced improvement as defined by **ONE** of the following?
- The patient has normalization of elevated serum or urine bile alcohols
- The patient has normalization of elevated serum cholestanol levels
- The patient has shown improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
If no, continue to #2.

Does the patient have a diagnosis of radiolucent gallstone(s) (ICD-10 Group K80.0) and meet **ALL** of the following criteria?
- The patient has NOT previously received a total duration of chenodiol therapy exceeding 24 months
- The patient has NOT experienced complete or zero gallstone dissolution, as seen on imaging (e.g., oral cholecystogram, ultrasonogram) after 12 months of therapy
- The patient has experienced partial gallstone dissolution, as seen on imaging (e.g., oral cholecystogram, ultrasonogram) after 12 months of therapy
- The request is for Chenodal

If yes, **approve Chenodal for 12 months by NDC (FDB) or GPI-10 with a quantity limit of #7 per day.**

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CHENODIOL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHENODIOL (Chenodal, Ctexli)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- Cerebrotendinous xanthomatosis (a type of genetic disorder)
- Radiolucent gallstone(s) (hardened deposits of bile in the gall bladder that are barely seen on X-rays [a type of imaging test])

If you have cerebrotendinous xanthomatosis, renewal also requires:
- You have experienced improvement as defined by ONE of the following:
  - Normalization of elevated (high levels of) serum (blood) or urine bile alcohols (a type of bile acid)
  - Normalization of elevated (high levels of) serum (blood) cholestanol (a type of fat) levels
  - Improvement in neurologic and psychiatric symptoms (dementia [a type of memory disorder], pyramidal tract [a nerve pathway in the brain] and cerebellar [brain] signs)

If you have radiolucent gallstone(s), renewal also requires:
- You have NOT previously received chenodiol therapy for more than a total of 24 months
- You have NOT experienced complete gallstone dissolution (breaking down) or zero gallstone dissolution, as seen on imaging (such as oral cholecystogram, ultrasonogram [types of imaging tests]) after 12 months of therapy
- You HAVE experienced partial gallstone dissolution (breaking down), as seen on imaging (such as oral cholecystogram, ultrasonogram [types of imaging tests]) after 12 months of therapy
- Your request is for Chenodal

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Chenodal and Ctexli.

REFERENCES
Chenodal [Prescribing Information]. San Diego, CA: Travere Therapeutics; December 2024.
Ctexli [Prescribing Information]. Foster City, CA: Mirum Pharmaceuticals, Inc.; February 2025.

Created: 11/09
Effective: 07/22/26 Client Approval: 07/26 P&T Approval: 07/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CHOLIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CHOLIC ACID	CHOLBAM	39124		GPI-10 (5270002500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have **ONE** of the following?
A bile acid synthesis disorder
A peroxisomal disorder (Zellweger spectrum disorder) (ICD-10 Group E71.5)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

Does the patient meet **ALL** of the following criteria?
Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
The patient exhibits manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption

If yes, **approve for 3 months by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for approval:
You have ONE of the following:
A bile acid synthesis disorder (a type of rare genetic condition)
A peroxisomal disorder (Zellweger spectrum disorder) (a type of rare genetic condition)
Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a doctor who treats digestive conditions)
You show signs or symptoms of liver disease, steatorrhea (excess fat in feces), or complications from your body not being able to absorb fat-soluble vitamins

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CHOLIC ACID

RENEWAL CRITERIA

Does the patient have **ONE** of the following?
- A bile acid synthesis disorder
- A peroxisomal disorder (Zellweger spectrum disorder) (ICD-10 Group E71.5)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

Has the patient experienced an improvement in liver function as defined by **ONE** of the following criteria?
- The patient's ALT (alanine aminotransferase) or AST (aspartate transaminase) values have been reduced to less than 50 U/L or the patient's baseline levels have been reduced by 80%
- The patient's total bilirubin values have been reduced to less than 1 mg/dL
- There is no evidence of cholestasis on liver biopsy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for renewal:
You have ONE of the following:
- A bile acid synthesis disorder (a type of rare genetic condition)
- A peroxisomal disorder (Zellweger spectrum disorder) (a type of rare genetic condition)

You have experienced an improvement in your liver function as defined by ONE of the following:
- Your ALT (alanine aminotransferase: a type of liver enzyme) or AST (aspartate transaminase: a type of liver enzyme) values have been reduced to less than 50 U/L or your baseline (before treatment) levels have been reduced by 80 percent
- Your total bilirubin value (a type of lab test) has been reduced to less than 1 mg/dL
- There is no evidence of cholestasis (condition where bile flow from the liver is reduced/blocked) on liver biopsy (removal of cells or tissue from the body for examination)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CHOLIC ACID

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cholbam.

REFERENCES

Cholbam [Prescribing Information]. San Diego, CA: Manchester Pharmaceuticals, Inc; March 2023.

Created: 04/15
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CIPAGLUCOSIDASE ALFA-ATGA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CIPAGLUCOSIDASE ALFA-ATGA	POMBILITI	49231		GPI-10 (3090773005)	

GUIDELINES FOR USE

Does the patient have a diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (ICD-10 E74.02) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient weighs at least 40 kgs (88 lbs.)
- The patient is not improving on their current enzyme replacement therapy (ERT) (e.g., Lumizyme [alglucosidase alfa])
- Pombiliti will be used in combination with Opfolda (miglustat)

If yes, **approve for lifetime by HICL or GPI-10 with a fill limit of #2 fills per 28 days.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CIPAGLUCOSIDASE ALFA-ATGA (Pombiliti)** requires the following rule(s) be met for approval:
- You have late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA deficiency) (a type of genetic disorder)
- You are 18 years of age or older
- You weigh at least 40 kilograms (88 pounds)
- You are NOT improving on your current enzyme replacement therapy (ERT) (such as Lumizyme [alglucosidase alfa])
- Pombiliti will be used in combination with Opfolda (miglustat)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pombiliti.

REFERENCES

Pombiliti [Prescribing Information]. Philadelphia, PA: Amicus Therapeutics US, LLC; July 2024.

Created: 11/23
Effective: 05/13/26 Client Approval: 05/26 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLADRIBINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLADRIBINE	MAVENCLAD		44338	GPI-10 (6240101500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including relapsing-remitting disease and active secondary progressive MS, **AND** meet the following criterion?
The patient is 18 years of age or older

If yes, **approve for 48 weeks by GPID or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for approval:
You have a relapsing form of multiple sclerosis (MS: type of nerve disorder), which includes relapsing-remitting disease (symptoms or disease returns and goes away) and active secondary progressive MS (advanced disease)
You are 18 years of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLADRIBINE

RENEWAL CRITERIA

Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including relapsing-remitting disease and active secondary progressive MS, **AND** meet the following criterion?
The patient has NOT received a total of two years of Mavenclad treatment (two yearly treatment courses of two cycles in each)

If yes, **approve for 48 weeks by GPID or GPI-10**.
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for renewal:
You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes relapsing-remitting disease (symptoms or disease returns and goes away) and active secondary progressive MS (advanced disease)
You have NOT received a total of two years of Mavenclad treatment (two yearly treatment courses of two cycles in each)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavenclad.

REFERENCES

Mavenclad [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; May 2024.

Created: 04/19
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLASCOTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLASCOTERONE	WINLEVI	46803		GPI-10 (9005001100)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Does the patient have a diagnosis of acne vulgaris (ICD-10 L70.0) and meet **ALL** of the following criteria?
The patient is 12 years of age or older
Winlevi will NOT be used concurrently with other single source brand acne agents (e.g., Aklief, Cabtreo)

If yes, **approve for 3 months by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:
A. You have acne vulgaris (a type of skin condition)
B. You are 12 years of age or older
C. You will NOT use Winlevi at the same time with other acne therapies that are only available as brand name (such as Aklief, Cabtreo)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLASCOTERONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acne vulgaris (ICD-10 L70.0) and meet **ALL** of the following criteria?
   - The patient has had an improvement in acne lesions
   - Winlevi will NOT be used concurrently with other single source brand acne agents (e.g., Aklief, Cabtreo)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for renewal:
   A. You have acne vulgaris (a type of skin condition)
   B. You have had an improvement in acne lesions
   C. You will NOT use Winlevi at the same time with other acne therapies that are only available as brand name (such as Aklief, Cabtreo)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Winlevi.

REFERENCES

Winlevi [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2022.

Created: 12/20
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CLONIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CLONIDINE HCL	JAVADIN	00113		GPI-10 (3620101010)	BRAND = JAVADIN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow clonidine tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CLONIDINE (Javadin)** requires the following rule(s) be met for approval:
   A. You have hypertension (high blood pressure)
   B. You are 18 years of age or older
   C. You have a contraindication to (harmful for you to use) or are unable to swallow clonidine tablets

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Javadin.

REFERENCES

Javadin [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; October 2025.

Created: 12/25
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COBIMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COBIMETINIB FUMARATE	COTELLIC	42796		GPI-10 (2153353020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor has a BRAF V600E OR V600K mutation
   - Cotellic will be used in combination with vemurafenib (Zelboraf)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #63 per 28 days.** If no, continue to #2.

2. Does the patient have a diagnosis of histiocytic neoplasm (ICD-10 C96.A, C96.0, C96.5, C96.6, D76.1, D76.3, J84.82) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #63 per 28 days.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COBIMETINIB (Cotellic)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)
      2. Hystiocytic neoplasm (a type of white blood cell disorder)

   B. If you have unresectable or metastatic melanoma, approval also requires:
      1. You are 18 years of age or older
      2. Your tumor has a BRAF V600E OR V600K mutation (a type of abnormal gene)
      3. Cotellic will be used in combination with vemurafenib (Zelboraf)

   C. If you have a histiocytic neoplasm, approval also requires:
      1. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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COBIMETINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cotellic.

REFERENCES

Cotellic [Prescribing Information]; S. San Francisco, CA: Genentech USA, Inc.; March 2023.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COLCHICINE - GLOPERBA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COLCHICINE	GLOPERBA		45974	GPI-14 (68000020002060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of gout flares (ICD-10 Group M10) and meet **ALL** of the following criteria?
   - Gloperba will be used for the prophylaxis of gout flares
   - The patient has a contraindication to or is unable to swallow colchicine tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COLCHICINE - GLOPERBA** requires the following rule(s) be met for approval:
   A. You have gout flares (episodes of pain or swelling associated with a type of joint condition)
   B. Gloperba will be used for the prophylaxis (preventive) of gout flares (episodes of pain or swelling associated with a type of joint condition)
   C. You have a contraindication to (harmful for you to use) or are unable to swallow colchicine tablets

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Gloperba.

REFERENCES
Gloperba [Prescribing Information]. Palo Alto, CA: SCILEX Pharmaceuticals, Inc.; August 2024.

Created: 05/26
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COLLAGENASE TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COLLAGENASE CLOSTRIDIUM HIST.	SANTYL		21190	GPI-14 (90700010004205)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic dermal ulcer(s) (ICD-10 Group L98.49) or severe burn(s) that require(s) debridement?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the requested quantity for one tube (30 grams) or less?

   If yes, **approve by GPID or GPI-14 for one fill with a quantity limit of #30 grams.**
   If no, continue to #3.

3. Are **BOTH** of the following provided?
   - The patient's wound size (width/length)
   - The anticipated duration of therapy

   If yes, **approve by GPID or GPI-14 for one fill with a quantity limit based on the Santyl dosing calculator (https://santyl.com/hcp/dosing).**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COLLAGENASE TOPICAL (Santyl)** requires the following rule(s) be met for approval:
   A. You have chronic dermal (skin) ulcer(s) or severe burn(s) that require(s) debridement (removal of damaged tissue from a wound)
   B. If the requested quantity is more than one tube (30 grams), approval also requires:
      1. The higher quantity is based on the size of your wound (width/length) and the anticipated duration of therapy, using the Santyl dosing calculator (https://santyl.com/hcp/dosing)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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COLLAGENASE TOPICAL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Santyl.

REFERENCES

Santyl [Prescribing Information]. Fort Worth, TX: Smith & Nephew, Inc., May 2019.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CONCIZUMAB-MTCI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CONCIZUMAB-MTCI	ALHEMO	50125		GPI-10 (8510502505)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0)
   - Hemophilia B (congenital factor IX deficiency) (ICD-10 D67)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   - Alhemo will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CONCIZUMAB-MTCI (Alhemo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
      2. Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   D. Alhemo will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   E. You will NOT use Alhemo concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CONCIZUMAB-MTCI

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0)
   - Hemophilia B (congenital factor IX deficiency) (ICD-10 D67)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Alhemo will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])
   - The patient has shown a clinical benefit compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CONCIZUMAB-MTCI (Alhemo)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
      2. Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)
   B. You will NOT use Alhemo concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq])
   C. You have shown a clinical benefit compared to baseline (before starting Alhemo)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alhemo.

REFERENCES

Alhemo [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc.; July 2025.

Created: 01/25
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CONTINUOUS BLOOD-GLUCOSE METER/RECEIVER	DEXCOM G4, DEXCOM G5 , MINIMED APP MANAGER	36756		GPI-10 (9720201202)	FDB & Medi-Span: BRAND = DEXCOM G4%, DEXCOM G5% FDB: MINIMED%
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G4, DEXCOM G5, EVERSENSE SMART TRANSMITTER, EVERSENSE E3 SMART TRANSMITTER, EVERSENSE 365 TRANSMITTER, GUARDIAN CONNECT TRANSMITTER, GUARDIAN LINK 3 TRANSMITTER, GUARDIAN 4 TRANSMITTER	36760		GPI-10 (9720201206)	FDB & Medi-Span: BRAND = DEXCOM G4%, DEXCOM G5%, EVERSENSE SMART TRANSMITTER, EVERSENSE E3 SMART TRANSMITTER, EVERSENSE 365 TRANSMITTER, GUARDIAN CONNECT TRANSMITTER, GUARDIAN LINK 3 TRANSMITTER, GUARDIAN 4 TRANSMITTER
BLOOD-GLUCOSE SENSOR	DEXCOM G5-G4 SENSOR, DEXCOM G4 SENSOR, GUARDIAN SENSOR 3, GUARDIAN 4 GLUCOSE SENSOR, EVERSENSE SENSOR-HOLDER, EVERSENSE E3 SENSOR-HLDR, EVERSENSE 365 SENSOR, MINIMED INSTINCT SENSOR, SIMPLERA SENSOR, SIMPLERA SYNC SENSOR	36696 45253		GPI-10 (9720201204)	FDB & Medi-Span: BRAND = DEXCOM G5-G4%, DEXCOM G4 SENSOR, GUARDIAN SENSOR 3, GUARDIAN 4 GLUCOSE SENSOR, EVERSENSE SENSOR-HOLDER, EVERSENSE E3 SENSOR-HLDR, EVERSENSE 365 SENSOR, MINIMED INSTINCT SENSOR, SIMPLERA SENSOR, SIMPLERA SYNC SENSOR

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of type 1, type 2, or gestational diabetes (ICD-10 Groups E08, E09, E10, E11, E13, O24.4)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is being treated with insulin (e.g., Humalog [insulin lispro], Lantus [insulin glargine])
   - The patient has a clinical need that cannot be managed with self-monitoring of blood glucose (SMBG) (e.g., frequent hypoglycemia, hypoglycemic unawareness, unable to achieve control of diabetes)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for Dexcom G4 or Dexcom G5 (meter, sensor, transmitter) **AND** the patient meets the following criterion?
   - The patient is 2 years of age or older

   If yes, continue to #8.
   If no, continue to #4.

4. Is the request for Guardian Connect (sensor, transmitter) **AND** the patient meets the following criterion?
   - The patient is 14 to 75 years of age

   If yes, continue to #8.
   If no, continue to #5.

5. Is the request for Guardian 3 (sensor, link transmitter), Guardian 4 (sensor, transmitter), Simplera Sensor, or Simplera Sync Sensor **AND** the patient meets the following criterion?
   - The patient is 7 years of age or older

   If yes, continue to #8.
   If no, continue to #6.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

INITIAL CRITERIA (CONTINUED)

6. Is the request for Eversense (sensor, smart transmitter), Eversense E3 (sensor, smart transmitter), or Eversense 365 (sensor, transmitter) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #8.
   If no, continue to #7.

7. Is the request for Minimed Instinct (sensor, receiver) **AND** the patient meets the following criterion?
   - The patient is 2 years of age or older

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

INITIAL CRITERIA (CONTINUED)

8. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agent: Dexcom G7
   - The patient had a trial of or contraindication to the preferred agent: Freestyle Libre
   - Dexcom G7 and Freestyle Libre are not compatible with the patient's current insulin pump

   If yes, **approve the requested device for 12 months by NDC as follows:**
   1. **Dexcom G4: approve all of the following:**
      - **Receiver: #1 per 12 months.**
      - **Transmitter: #1 per 180 days.**
      - **Sensor: #4 per 28 days.**
   2. **Dexcom G5: approve all of the following:**
      - **Receiver: #1 per 12 months.**
      - **Transmitter: #1 per 90 days.**
      - **Sensor: #4 per 28 days.**
   3. **Guardian Connect: approve all of the following:**
      - **Transmitter: #1 per 12 months.**
      - **Sensor: #5 per 35 days.**
   4. **Guardian 3: approve all of the following:**
      - **Link Transmitter: #1 per 12 months.**
      - **Sensor: #5 per 35 days.**
   5. **Guardian 4: approve all of the following:**
      - **Transmitter: #1 per 12 months.**
      - **Sensor: #5 per 35 days.**
   6. **Minimed Instinct:**
      - **Receiver: #1 per 12 months.**
      - **Sensor: #2 per 30 days.**
   7. **Simplera Sensor:**
      - **Sensor: #5 per 35 days.**
   8. **Simplera Sync Sensor:**
      - **Sensor: #5 per 35 days.**
   9. **Eversense: approve all of the following:**
      - **Smart transmitter: #1 per 12 months.**
      - **Sensor: #1 per 90 days.**
   10. **Eversense E3: approve all of the following:**
      - **Smart transmitter: #1 per 12 months.**
      - **Sensor: #1 per 180 days.**
   11. **Eversense 365: approve all of the following:**
      - **Transmitter: #1 per 12 months.**
      - **Sensor: #1 per 12 months.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CONTINUOUS GLUCOSE MONITORS - STAND-ALONE** requires the following rule(s) be met for approval:

A. You have type 1, type 2, or gestational (during pregnancy) diabetes (a disorder with high blood sugar)
B. You have tried or have a contraindication to (harmful for you to use) one of the preferred products: Dexcom G7 or Freestyle Libre, OR both products are not compatible with your current insulin pump
C. You meet ONE of the following:
    1. You are being treated with insulin (such as Humalog [insulin lispro], Lantus [insulin glargine])
    2. You have a clinical need that cannot be managed with self-monitoring of blood glucose (such as frequent hypoglycemia [low blood sugar], hypoglycemic unawareness, unable to achieve control of diabetes)
D. If you are requesting Dexcom G4 or Dexcom G5 system (meter, sensor, transmitter), or Minimed Instinct (sensor, receiver), approval also requires:
    1. You are 2 years of age or older
E. If you are requesting Guardian Connect (sensor, transmitter), approval also requires:
    1. You are 14 to 75 years of age
F. If you are requesting Guardian 3 (sensor, link transmitter), Guardian 4 (sensor, transmitter), Simplera Sensor, or Simplera Sync Sensor, approval also requires:
    1. You are 7 years of age or older
G. If you are requesting Eversense (sensor, smart transmitter), Eversense E3 (sensor, smart transmitter) or Eversense 365 (sensor, transmitter), approval also requires:
    1. You are 18 years of age or older

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

RENEWAL CRITERIA

1. Does the patient continue to require continuous glucose monitoring?

If yes, **approve the requested device for 12 months by NDC as follows:**

1. **Dexcom G4: approve all of the following:**
   - **Receiver: #1 per 12 months.**
   - **Transmitter: #1 per 180 days.**
   - **Sensor: #4 per 28 days.**
2. **Dexcom G5: approve all of the following:**
   - **Receiver: #1 per 12 months.**
   - **Transmitter: #1 per 90 days.**
   - **Sensor: #4 per 28 days.**
3. **Guardian Connect: approve all of the following:**
   - **Transmitter: #1 per 12 months.**
   - **Sensor: #5 per 35 days.**
4. **Guardian 3: approve all of the following:**
   - **Link Transmitter: #1 per 12 months.**
   - **Sensor: #5 per 35 days.**
5. **Guardian 4: approve all of the following:**
   - **Transmitter: #1 per 12 months.**
   - **Sensor: #5 per 35 days.**
6. **Minimed Instinct:**
   - **Receiver: #1 per 12 months.**
   - **Sensor: #2 per 30 days.**
7. **Simplera Sensor:**
   - **Sensor: #5 per 35 days.**
8. **Simplera Sync Sensor:**
   - **Sensor: #5 per 35 days.**
9. **Eversense: approve all of the following:**
   - **Smart transmitter: #1 per 12 months.**
   - **Sensor: #1 per 90 days.**
10. **Eversense E3: approve all of the following:**
    - **Smart transmitter: #1 per 12 months.**
    - **Sensor: #1 per 180 days.**
11. **Eversense 365: approve all of the following:**
    - **Transmitter: #1 per 12 months.**
    - **Sensor: #1 per 12 months.**

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CONTINUOUS GLUCOSE MONITORS - STAND-ALONE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CONTINUOUS GLUCOSE MONITORS - STAND-ALONE** requires the following rule(s) be met for renewal:
A. You continue to require continuous glucose monitoring

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related continuous glucose monitor.

REFERENCES

Dexcom Continuous Glucose Monitoring Products. Dexcom, Inc. Available at: https://www.dexcom.com/
Medtronic. Medtronic MiniMed, Inc. Available at: https://www.medtronicdiabetes.com/products/guardian-connect-continuous-glucose-monitoring-system
Eversense Continuous Glucose Monitoring System. Senseonics, Inc. Available at: https://www.eversensediabetes.com/
Minimed Instinct Sensor. Medtronic MiniMed, Inc. Available at: https://www.medtronicdiabetes.com/loop-blog/introducing-instinct-sensor
Minimed App Manager. Medtronic MiniMed, Inc. Available at: https://www.minimed.com/en-us/support/app-manager

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CONTINUOUS GLUCOSE MONITORS STEP OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CONTINUOUS BLOOD-GLUCOSE METER/RECEIVER, FLASH GLUCOSE SCANNING READER	DEXCOM G6, G7 RECEIVER, FREESTYLE LIBRE 2, 3, 10, 14 READER	36756 44578		GPI-10 (9720201202)	FDB & Medi-Span: BRAND = DEXCOM G6%, G7%, FREESTYLE LIBRE%
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G6 TRANSMITTER	36760		GPI-10 (9720201206)	FDB & Medi-Span: BRAND = DEXCOM G6%
BLOOD-GLUCOSE SENSOR, CONTINUOUS GLUCOSE SYSTEM SENSOR	DEXCOM G6, G7 SENSOR, DEXCOM G7 15 DAY SENSOR, FREESTYLE LIBRE 2, 3 PLUS SENSOR	36696		GPI-10 (9720201204)	FDB & Medi-Span: BRAND = DEXCOM G6%, G7%, FREESTYLE LIBRE%
FLASH GLUCOSE SENSOR, BLOOD GLUCOSE SENSOR	FREESTYLE LIBRE 2, 3, 10, 14 SENSOR	44576			Medi-Span: BRAND = FREESTYLE LIBRE%

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient is being treated with insulin (e.g., Humalog [insulin lispro], Lantus [insulin glargine])
   - The patient has a clinical need that cannot be managed with self-monitoring of blood glucose (SMBG) (e.g., frequent hypoglycemia, hypoglycemic unawareness, unable to achieve control of diabetes)
   - The patient is currently stable on the requested agent while covered by their current or previous health plan

   If yes, **approve the requested agent for 12 months by HICL or GPI-10 as follows:**
   - **Dexcom G6: approve all of the following: Receiver, Transmitter, and Sensor.**
   - **Dexcom G7: approve both of the following: Receiver and Sensor.**
   - **FreeStyle Libre system: approve both of the following: Reader and Sensor.**

   NOTE TO PAC: Override using the Step therapy edit only. Do not override any quantity limit without review. All other rejections will require clinical review.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CONTINUOUS GLUCOSE MONITORS STEP OVERRIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CONTINUOUS GLUCOSE MONITORS STEP OVERRIDE** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are being treated with insulin (such as Humalog [insulin lispro], Lantus [insulin glargine])
   2. You have a clinical need that cannot be managed with self-monitoring of blood glucose (such as frequent hypoglycemia [low blood sugar], hypoglycemic unawareness, unable to achieve control of diabetes [a disorder with high blood sugar])
   3. You are currently stable on the requested agent

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related continuous glucose monitor.

REFERENCES

FreeStyle Libre Flash Glucose Monitoring System, Freestyle Libre System. Abbott Laboratories. Indications and Safety Information. Available at: https://www.freestyle.abbott/us-en/home.html

Dexcom Continuous Glucose Monitoring Products. Dexcom, Inc. Available at: https://www.dexcom.com/

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COPPER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COPPER HISTIDINATE	ZYCUBO	51085		GPI-10 (7990001016)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Menkes disease (ICD-10 E83.09) **AND** meet the following criterion?
   - The patient is 17 years of age or younger

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COPPER (Zycubo)** requires the following rule(s) be met for approval:
   A. You have Menkes disease (a type of genetic disorder)
   B. You are 17 years of age or younger

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zycubo.

REFERENCES

Zycubo [Prescribing Information]. Solana Beach, CA: Sentynl Therapeutics, Inc.; January 2026.

Created: 02/26
Effective: 02/07/26 Client Approval: 02/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CORTICOTROPIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CORTICOTROPIN	ACTHAR , ACTHAR SELFJECT, CORTROPHIN	02830		GPI-10 (3030001000)	

GUIDELINES FOR USE

1. Is the request for Acthar pre-filled SelfJect or Cortrophin pre-filled syringe for any indication?

   If yes, do not approve.
   Note: Off-label guideline should not be used because these agents haven't demonstrated proven benefits in the other indications and have no proven advantage over synthetic steroids. Therefore, there isn't a pathway to approval for any other listed indications.

   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) **AND** meet the following criterion?
   - The patient is less than 2 years of age

   If yes, **approve Acthar or Cortrophin vial for 28 days by GPID or GPI-14 for #40mL.**
   If no, continue to #3.

3. Is the request for any other indications other than infantile spasms?

   If yes, do not approve. See note below and use the denial text at the end of the guideline.
   Note: Off-label guideline should not be used because these agents haven't demonstrated proven benefits in the other indications and have no proven advantage over synthetic steroids. Therefore, there isn't a pathway to approval for any other listed indications.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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CORTICOTROPIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CORTICOTROPIN (Acthar, Cortrophin)** requires the following rule(s) be met for approval:

A. You have infantile spasms (a type of seizure disorder in infancy and childhood)
B. You are less than 2 years of age
C. Your request is for Acthar or Cortrophin vial

Acthar or Cortrophin vial will not be approved for any other indication other than infantile spasms. Acthar or Cortrophin have not demonstrated proven benefits or advantage over synthetic steroids in the treatment of other indications.

Acthar pre-filled SelfJect or Cortrophin pre-filled syringe will not be approved for infantile spasms (not Food and Drug Administration [FDA]-indicated) or any other indication. Acthar or Cortrophin have not demonstrated proven benefits or advantage over synthetic steroids in the treatment of other indications.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Acthar Gel or Purified Cortrophin Gel.

REFERENCES

Acthar Gel [Prescribing Information]. Bridgewater, NJ: Mallinckrodt ARD LLC; February 2024.
Purified Cortrophin Gel [Prescribing Information]. Baudette, MN: ANI Pharmaceuticals, Inc.; February 2025.

Created: 11/07
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COSIBELIMAB-IPDL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COSIBELIMAB-IPDL	UNLOXCYT	50094		GPI-10 (2135822601)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced cutaneous squamous cell carcinoma (laCSCC) (ICD-10 C44.02, C44.42, C44.82, C44.92; Groups C44.12, C44.22, C44.32, C44.52, C44.62, C44.72) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is not a candidate for curative surgery or curative radiation

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **COSIBELIMAB-IPDL (Unloxcyt)** requires the following rule(s) be met for approval:
   A. You have metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) (a type of skin cancer that has spread to other parts of the body or to nearby tissue or lymph nodes)
   B. You are 18 years of age or older
   C. You are not a candidate for curative (cure) surgery or curative radiation

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Unloxcyt.

REFERENCES

Unloxcyt [Prescribing Information]. Waltham, MA: Checkpoint Therapeutics, Inc.; December 2024.

Created: 09/25
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRINECERFONT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRINECERFONT	CRENESSITY	50097		GPI-10 (3032102000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of classic congenital adrenal hyperplasia (CAH) and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Crenessity will be used as adjunctive treatment with glucocorticoid replacement therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for Crenessity capsule?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **25mg capsule: #3 per day.**
   - **50mg capsule: #3 per day.**
   - **100mg capsule: #4 per day.**

   If no, continue to #3.

3. Is the request for Crenessity solution **AND** the patient meets the following criterion?
   - The patient is unable to swallow Crenessity capsules

   If yes, **approve the solution for 12 months by GPID or GPI-14 with a quantity limit of #8mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CRINECERFONT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CRINECERFONT (Crenessity)** requires the following rule(s) be met for approval:

A. You have classic congenital adrenal hyperplasia (CAH: a type of rare genetic condition)
B. You are 4 years of age or older
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Crenessity will be used as adjunctive (additional) treatment with glucocorticoid (a type of steroid medication) replacement therapy
E. If the request is for Crenessity solution, approval also requires:
   1. You are unable to swallow Crenessity capsules

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CRINECERFONT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of classic congenital adrenal hyperplasia (CAH) **AND** meet the following criterion?
   - The patient has experienced clinical benefit (e.g., decreased androstenedione levels, reduction in glucocorticoid daily dose from baseline, improvement or stabilization in CAH symptoms)

   If yes, **approve all strengths of the requested formulation for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **25mg capsule: #3 per day.**
   - **50mg capsule: #3 per day.**
   - **100mg capsule: #4 per day.**
   - **50mg/mL solution: #8mL per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CRINECERFONT (Crenessity)** requires the following rule(s) be met for renewal:
   A. You have classic congenital adrenal hyperplasia (CAH: a type of rare genetic condition)
   B. You have experienced a clinical benefit (such as decreased androstenedione levels [a type of lab test], reduction in glucocorticoid [a type of steroid medication] daily dose from baseline [before treatment], improvement in or stabilization of congenital adrenal hyperplasia [a type of rare genetic condition] symptoms)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Crenessity.

REFERENCES

Crenessity [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; December 2024.

Created: 12/24
Effective: 04/29/26 Client Approval: 04/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRISABOROLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRISABOROLE	EUCRISA	43999		GPI-10 (9023002500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) and meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to the clinical standard of care agent: a topical corticosteroid (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
   - The patient had a trial of or contraindication to the preferred agent: a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CRISABOROLE (Eucrisa)** requires the following rule(s) be met for approval:
   A. You have mild to moderate atopic dermatitis (a type of skin condition)
   B. You meet ONE of the following:
      1. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
      2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRISABOROLE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?

- The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CRISABOROLE (Eucrisa)** requires the following rule(s) be met for renewal:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting dermatitis (a type of skin condition that returns and goes away), or facial/interdigital (between the fingers or toes) involvement

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eucrisa.

REFERENCES

Eucrisa [Prescribing Information]. New York, NY: Pfizer Labs; April 2023.

Created: 10/25
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRIZANLIZUMAB-TMCA (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRIZANLIZUMAB-TMCA	ADAKVEO	46209		GPI-10 (8280702070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sickle cell disease and meet **ALL** of the following criteria?
   - The medication is prescribed by or given in consultation with a hematologist
   - The patient had a trial of or contraindication to hydroxyurea

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient between the ages of 16 to 17 years old?

   If yes, **approve for 12 months by HICL or GPI-10 for #1 fill every 4 weeks.**
   APPROVAL TEXT: Renewal requires that the patient has maintained or experienced a reduction in acute complications of sickle cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, acute chest syndrome [ACS]).

   If no, continue to #3.

3. Is the patient 18 years of age or older and meet **ONE** of the following criteria?
   - The patient had at least 2 sickle cell crises in the past year (a sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome, priapism, or splenic sequestration)
   - The patient is having sickle cell associated symptoms (e.g., pain or anemia) which are interfering with activities of daily living
   - The patient has a history of or has recurrent acute chest syndrome (ACS)

   If yes, **approve for 12 months by HICL or GPI-10 for #1 fill every 4 weeks.**
   APPROVAL TEXT: Renewal requires that the patient has maintained or experienced a reduction in acute complications of sickle cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, acute chest syndrome [ACS]).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CRIZANLIZUMAB-TMCA (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CRIZANLIZUMAB-TMCA (Adakveo)** requires the following rule(s) be met for approval:

A. You have sickle cell disease (type of red blood cell disorder)
B. You are at least 16 years old
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist)
D. You have previously tried hydroxyurea, unless there is a medical reason why you cannot (contraindication)
E. If you are 18 years of age or older, approval also requires ONE of the following:
   1. You had at least 2 sickle cell crises in the past year. (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered (given into the vein) narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
   2. You are having sickle cell associated symptoms (such as pain or anemia) which are interfering with activities of daily living
   3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever and low oxygen levels)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sickle cell disease **AND** meet the following criterion?
   - The patient has maintained or experienced a reduction in acute complications of sickle-cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, acute chest syndrome [ACS])

   If yes, **approve for lifetime by HICL or GPI-10 for #1 fill every 4 weeks.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CRIZANLIZUMAB-TMCA (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CRIZANLIZUMAB-TMCA (Adakveo)** requires the following rule(s) be met for renewal:

A. You have sickle cell disease (type of red blood cell disorder)
B. You have maintained or experienced a reduction in acute (sudden and severe) complications of sickle cell disease (SCD) (such as a reduction in number of sickle cell crises, hospitalizations, acute chest syndrome [ACS: chest pain, cough, fever and low oxygen levels]).

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adakveo.

REFERENCES

Adakveo [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; November 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 11/19
Client Approval: 02/20
P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CRIZOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CRIZOTINIB	XALKORI	37916		GPI-10 (2153051700)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient's tumor is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
   - The patient's tumor is ROS1-positive as detected by an FDA-approved test

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient unable to swallow capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **50mg pellet: #4 per day.**
   - **150mg pellet: #2 per day.**

   If no, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **200mg capsule: #2 per day.**
   - **250mg capsule: #2 per day.**

4. Does the patient have a diagnosis of relapsed or refractory systemic anaplastic large cell lymphoma (ALCL) (ICD-10 Group C84.6) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's tumor is anaplastic lymphoma kinase (ALK)-positive

   If yes, continue to #6.
   If no, continue to #5.

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CRIZOTINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's tumor is anaplastic lymphoma kinase (ALK)-positive

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is the patient unable to swallow capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **20mg pellet: #8 per day.**
   - **50mg pellet: #4 per day.**
   - **150mg pellet: #6 per day.**

   If no, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **200mg capsule: #4 per day.**
   - **250mg capsule: #4 per day.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CRIZOTINIB (Xalkori)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
      2. Relapsed (disease that has returned) or refractory (disease does not respond to treatment), systemic anaplastic large cell lymphoma (ALCL: a type of blood cell cancer)
      3. Unresectable (unable to remove by surgery), recurrent, or refractory (disease does not respond to treatment) inflammatory myofibroblastic tumor (IMT: a rare type of tumor)

   B. If you have metastatic non-small cell lung cancer, approval also requires:
      1. You are 18 years of age or older
      2. Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme)-positive or ROS1 (a type of gene)-positive as detected by a Food and Drug Administration (FDA)-approved test

   C. If you have relapsed or refractory systemic anaplastic large cell lymphoma, approval also requires:
      1. You are 1 year of age or older
      2. Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

   (Denial text continued on next page)

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CRIZOTINIB

GUIDELINES FOR USE (CONTINUED)

D. If you have unresectable, recurrent, or refractory inflammatory myofibroblastic tumor, approval also requires:
1. You are 1 year of age or older
2. Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme)-positive

E. If the request is for Xalkori oral pellets, approval also requires:
1. You are unable to swallow capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xalkori.

REFERENCE

Xalkori [Prescribing Information]. New York, New York: Pfizer Inc.; September 2023.

Created: 09/11
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CROVALIMAB-AKKZ (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CROVALIMAB-AKKZ	PIASKY	49703		GPI-10 (8580503030)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient weighs at least 40 kgs (88 lbs)
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent
   - The patient has tried and failed (as evidenced by hemoglobin levels less than 10.5 g/dL directly following at least 3 months of stable dosing) or has a contraindication to Ultomiris (ravulizumab-cwvz)
   - Piasky will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #18mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #6mL per 28 days (Please enter a start date of 3 days BEFORE the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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CROVALIMAB-AKKZ (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CROVALIMAB-AKKZ (Piasky)** requires the following rule(s) be met for approval:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
B. You are 13 years of age or older
C. You weigh at least 40 kilograms (88 pounds)
D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
E. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
F. You have tried and failed (as shown by hemoglobin [type of protein in red blood cells] levels less than 10.5 g/dL immediately following at least 3 months of stable dosing) or have a contraindication to (harmful for you to use) Ultomiris (ravulizumab-cwvz)
G. You will NOT use Piasky concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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CROVALIMAB-AKKZ (NSA)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has had a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase and hemoglobin levels) compared to baseline
   - Piasky will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CROVALIMAB-AKKZ (Piasky)** requires the following rule(s) be met for renewal:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   B. You have experienced a clinical benefit (such as reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [an enzyme] and hemoglobin [type of protein in red blood cells] levels) compared to baseline (before you started treatment)
   C. You will NOT use Piasky concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Piasky.

REFERENCES

Piasky [Prescribing Information]. South San Francisco, CA: Genentech; June 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A Created: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYCLOSPORINE - VERKAZIA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYCLOSPORINE	VERKAZIA		46848	GPI-14 (86720020001630)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of vernal keratoconjunctivitis (ICD-10 Group H16.26) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient had a trial of or contraindication to TWO clinical standard of care agents: ophthalmic dual-acting mast cell stabilizer/antihistamines (e.g., ketotifen), mast cell stabilizers (e.g., cromolyn)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 vials per day.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYCLOSPORINE - VERKAZIA** requires the following rule(s) be met for approval:
   A. You have vernal keratoconjunctivitis (allergic eye disease)
   B. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
   C. You have tried or have a contraindication to (harmful for you to use) TWO clinical standard of care medications: ophthalmic dual-acting mast cell stabilizer/antihistamines (such as ketotifen), mast cell stabilizers (such as cromolyn)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verkazia.

REFERENCES

Verkazia [Prescribing Information]. Nashville, TN: Harrow Eye, LLC; January 2026.

Created: 08/22
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYCLOSPORINE - VEVYE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYCLOSPORINE	VEVYE	04524		GPI-10 (8672002000)	BRAND = VEVYE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of dry eye disease (DED) (ICD-10 Group H04.12) and meet **ALL** of the following criteria?

- Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
- The patient has at least ONE positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test)
- The patient had a trial of or contraindication to ONE clinical standard of care agent: an ocular lubricant (e.g., carboxymethylcellulose [Refresh, Celluvisc, TheraTears], polyvinyl alcohol [LiquiTears, Refresh Classic], wetting agent [Systane, Lacri-Lube])
- The patient had a trial of or contraindication to TWO of the following preferred agents: Miebo (perfluorohexyloctane), Restasis (cyclosporine), Xiidra (lifitegrast), Tyrvaya (varenicline), Tryptyr (acoltremon)

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #2mL per 30 days.** If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CYCLOSPORINE - VEVYE** requires the following rule(s) be met for approval:

A. You have dry eye disease (DED: a type of eye condition)
B. Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctors)
C. You have at least ONE positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test)
D. You have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: an ocular lubricant (such as carboxymethylcellulose [such as Refresh, Celluvisc, TheraTears], polyvinyl alcohol [such as LiquiTears, Refresh Classic], wetting agent [such as Systane, Lacri-Lube])
E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Miebo (perfluorohexyloctane), Restasis (cyclosporine), Xiidra (lifitegrast), Tyrvaya (varenicline), Tryptyr (acoltremon)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYCLOSPORINE – VEVYE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of dry eye disease (DED) (ICD-10 Group H04.12) **AND** meet the following criterion?
   - The patient has demonstrated improvement of dry eye disease

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per 30 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYCLOSPORINE - VEVYE** requires the following rule(s) be met for renewal:
   A. You have dry eye disease (DED: a type of eye condition)
   B. You have demonstrated improvement of your dry eye disease (the treatment is working)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vevye.

REFERENCES

Vevye [Prescribing Information]. Nashville, TN: Harrow Eye, LLC.; February 2026.

Created: 12/23
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE BITARTRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYSTEAMINE BITARTRATE	PROCYSBI		34656 34657 47723 47724	GPI-14 (56400030106520, 56400030106530, 56400030103020, 56400030103040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of nephropathic cystinosis (ICD-10 E72.04) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYSTEAMINE BITARTRATE (Procysbi)** requires the following rule(s) be met for approval:
   A. You have nephropathic cystinosis (a type of genetic disease)
   B. You are 1 year of age or older
   C. You have tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Procysbi.

REFERENCES

Procysbi [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; February 2022.

Created: 08/13
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 11/15

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE HYDROCHLORIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYSTEAMINE HCL	CYSTARAN, CYSTADROPS	37567		GPI-10 (8680552510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystinosis (ICD-10 E72.04) **AND** meet the following criterion?
   - The patient has corneal cystine crystal accumulation or deposits

   If yes, **approve the requested drug for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **Cystaran: #60 mL (4 bottles) per 28 days.**
   - **Cystadrops: #20 mL (4 bottles) per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran, Cystadrops)** requires the following rule(s) be met for approval:
   A. You have cystinosis (a type of genetic disorder)
   B. You have corneal cystine crystal accumulation or deposits (buildup of a type of amino acid in the eye)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystaran and Cystadrops.

REFERENCES

Cystaran [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences, Inc.; May 2023.
Cystadrops [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases Inc.; August 2020.

Created: 05/13
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 05/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DABIGATRAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DABIGATRAN ETEXILATE MESELATE	PRADAXA	35604		GPI-10 (8333703020)	DOSAGE FORM = PELET PACK (FDB), PACK (Medi-Span)

GUIDELINES FOR USE

1. Is the request for the treatment of a venous thromboembolic event (VTE) (ICD-10 Groups I82.4, I82.5, I82.62, I82.72, I82.9, I26) **AND** the patient meets the following criterion?
   - The patient has been treated with a parenteral anticoagulation agent for at least 5 days

   If yes, continue to #3.
   If no, continue to #2.

2. Is the request to reduce the risk of venous thromboembolic event (VTE) recurrence **AND** the patient meets the following criterion?
   - The patient has been previously treated

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 3 months to 7 years of age
   - The patient is 8 to 11 years of age AND unable to swallow dabigatran (Pradaxa) capsules

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

4. Has the patient had a trial of or contraindication to BOTH of the following preferred agents: rivaroxaban (Xarelto) suspension AND Eliquis (apixaban) sprinkle capsules/tablets oral suspension?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

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DABIGATRAN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DABIGATRAN (Pradaxa)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Treatment of a venous thromboembolic event (VTE: blood clot in the veins)
   2. To reduce the risk of venous thromboembolic event recurrence (happening again)

B. If the request is for the treatment of a venous thromboembolic event, approval also requires:
   1. You have been treated with a parenteral (injected into the vein) anticoagulation medication (type of medication to prevent blood clots) for at least 5 days
   2. You meet ONE of the following:
      a. You are 3 months to 7 years of age
      b. You are 8 to 11 years of age AND are unable to swallow dabigatran (Pradaxa) capsules
   3. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: rivaroxaban (Xarelto) suspension AND Eliquis (apixaban) sprinkle capsules/tablets oral suspension

C. If the request is to reduce the risk of venous thromboembolic event recurrence, approval also requires:
   1. You have been previously treated
   2. You meet ONE of the following:
      a. You are 3 months to 7 years of age
      b. You are 8 to 11 years of age AND are unable to swallow dabigatran (Pradaxa) capsules
   3. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: rivaroxaban (Xarelto) suspension AND Eliquis (apixaban) sprinkle capsules/tablets oral suspension

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pradaxa.

REFERENCES

Pradaxa [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2025.

Created: 10/10
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DABRAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DABRAFENIB MESYLATE	TAFINLAR	40360		GPI-10 (2153202510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ONE** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test AND Tafinlar will be used as a single agent
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test AND Tafinlar will be used in combination with Mekinist (trametinib)

   If yes, continue to #7.
   If no, continue to #2.

2. Does the patient have a diagnosis of melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - Tafinlar has not previously been used for more than one year
   - Tafinlar will be used in combination with Mekinist (trametinib) for adjuvant treatment
   - There is involvement of lymph node(s) following complete resection

   If yes, continue to #7.
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - Tafinlar will be used in combination with Mekinist (trametinib)

   If yes, continue to #7.
   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation
   - Tafinlar will be used in combination with Mekinist (trametinib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, continue to #7.
   If no, continue to #5.

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a BRAF V600E mutation
   - Tafinlar will be used in combination with Mekinist (trametinib)
   - The patient's disease has progressed following prior treatment and have no satisfactory alternative treatment options

   If yes, continue to #7.
   If no, continue to #6.

6. Does the patient have a diagnosis of low-grade glioma (LGG) (ICD-10 D33.2) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient has a BRAF V600E mutation
   - Tafinlar will be used in combination with Mekinist (trametinib)
   - The patient requires systemic therapy

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the request for the capsule formulation?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, continue to #8.

8. Is the request for the tablet for oral suspension **AND** the patient meets the following criterion?
   - The patient cannot swallow Tafinlar (dabrafenib) capsules

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DABRAFENIB (Tafinlar)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   2. Melanoma (a type of skin cancer)
   3. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread from where it started to nearby tissue or lymph nodes, or it has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be completely removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. If you have unresectable or metastatic melanoma, approval also requires ONE of the following:
   1. You have a BRAF V600E mutation (type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test AND Tafinlar will be used as a single agent (by itself)
   2. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by a Food and Drug Administration (FDA)-approved test AND Tafinlar will be used in combination with Mekinist (trametinib)

C. If you have melanoma, approval also requires:
   1. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by a Food and Drug Administration (FDA)-approved test
   2. Tafinlar has not previously been used for more than one year
   3. Tafinlar will be used in combination with Mekinist (trametinib) for adjuvant (additional) treatment
   4. There is involvement of lymph node(s) following complete resection (removal by surgery)

D. If you have metastatic non-small cell lung cancer, approval also requires:
   1. You have a BRAF V600E mutation (type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test
   2. Tafinlar will be used in combination with Mekinist (trametinib)

(Denial text continued on next page)

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DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

E. If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:
1. You have a BRAF V600E mutation (type of gene mutation)
2. Tafinlar will be used in combination with Mekinist (trametinib)
3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

F. If you have an unresectable or metastatic solid tumor, approval also requires:
1. You are 1 year of age or older
2. You have a BRAF V600E mutation (type of gene mutation)
3. Tafinlar will be used in combination with Mekinist (trametinib)
4. Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

G. If you have low-grade glioma, approval also requires:
1. You are 1 to 17 years of age
2. You have a BRAF V600E mutation (type of gene mutation)
3. Tafinlar will be used in combination with Mekinist (trametinib)
4. You require systemic therapy (treatment that targets the entire body)

H. If the request is for the tablet for oral suspension, approval also requires:
1. You cannot swallow Tafinlar (dabrafenib) capsules

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tafinlar.

REFERENCES

Tafinlar [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.

Created: 06/13
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DACOMITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DACOMITINIB	VIZIMPRO	45283		GPI-10 (2136001900)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34)and meet **ALL** of the following criteria?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
   - Vizimpro will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DACOMITINIB (Vizimpro)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   B. Your tumor has epidermal growth factor receptor (EGFR: a type of protein) exon 19 deletion or exon 21 L858R substitution mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   C. You will NOT use Vizimpro concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Iressa [gefitinib])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vizimpro.

REFERENCES

Vizimpro [Prescribing Information]. New York, NY: Pfizer Labs; December 2020.

Created: 11/18
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DALFAMPRIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DALFAMPRIDINE	AMPYRA, DALFAMPRIDINE ER	13907		GPI-10 (6240603000)	FDB: ROUTE MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of multiple sclerosis (MS) (ICD-10 G35) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has symptoms of a walking disability (e.g., mild to moderate bilateral lower extremity weakness, unilateral weakness plus lower extremity or truncal ataxia)

   If yes, **approve for 3 months by HICL or GPI-10 for #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for approval:
   A. You have multiple sclerosis (MS: a type of nerve disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   D. You have symptoms of a walking disability (such as mild to moderate bilateral [both sides] lower extremity weakness, unilateral [one side] weakness with lower extremity or truncal ataxia [impaired balance or coordination])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DALFAMPRIDINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of multiple sclerosis (MS) (ICD-10 G35) **AND** meet the following criterion?
   - The patient has experienced or maintained at least a 15% improvement in walking ability

   If yes, **approve for 12 months by HICL or GPI-10 for #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for renewal:
   A. You have multiple sclerosis (MS: a type of nerve disorder)
   B. You have experienced or maintained at least a 15% improvement in walking ability

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ampyra.

REFERENCES

Ampyra [Prescribing Information]. Ardsley, NY: Acorda Therapeutics; October 2023.

Created: 02/10
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DANICOPAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DANICOPAN	VOYDEYA	49483		GPI-10 (8580852000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - Voydeya will be used for the treatment of extravascular hemolysis (EVH)
   - The patient has anemia (Hgb level less than or equal to 9.5 g/dL) with an absolute reticulocyte count of at least 120 x 10^9/L
   - The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent
   - The patient had a trial of or contraindication to the preferred agent: Fabhalta (iptacopan)
   - Voydeya will be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
   - Voydeya will NOT be used concurrently with C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DANICOPAN (Voydeya)** requires the following rule(s) be met for approval:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   D. You will use Voydeya for the treatment of extravascular hemolysis (EVH: break down of blood cells outside of your blood stream)
   E. You have anemia (a hemoglobin [Hgb: a type of protein in red blood cells] level less than or equal to 9.5 g/dL) with an absolute reticulocyte (immature red blood cell) count of at least 120 x 10(9)/L

   (Initial denial text continued on next page)

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DANICOPAN

INITIAL CRITERIA (CONTINUED)

F. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
G. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Fabhalta (iptacopan)
H. You will use Voydeya concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
I. You will NOT use Voydeya concurrently (at the same time) with C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DANICOPAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit (e.g., improvement in hemoglobin levels) compared to baseline
   - Voydeya will be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
   - Voydeya will NOT be used concurrently with C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DANICOPAN (Voydeya)** requires the following rule(s) be met for renewal:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   B. You have experienced a clinical benefit (such as an improvement in hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before you started treatment)
   C. You will use Voydeya concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab])
   D. You will NOT use Voydeya concurrently (at the same time) with C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voydeya.

REFERENCES

Voydeya [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2024.

Created: 04/24
Effective: 06/10/26 Client Approval: 06/26 P&T Approval: 07/24

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DAPRODUSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DAPRODUSTAT	JESDUVROQ	48668		GPI-10 (8240252000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been receiving dialysis for at least 4 months
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient has an eGFR of less than 60 mL/min/1.73m(2) corresponding to stage 3, 4, or 5 chronic kidney disease (CKD)
   - Jesduvroq will NOT be used concurrently with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (e.g., Vafseo [vadadustat]) OR erythropoiesis-stimulating agents (ESAs) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient currently being treated with an erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa])?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have a hemoglobin level of less than 11 g/dL?

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
   - **1mg: #1 per day.**
   - **2mg: #1 per day.**
   - **4mg: #1 per day.**
   - **6mg: #2 per day.**
   - **8mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DAPRODUSTAT

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ALL** of the following criteria?
   - The patient has a hemoglobin level of less than 12 g/dL
   - The patient will discontinue the erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa]) prior to starting Jesduvroq

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
   - **1mg: #1 per day.**
   - **2mg: #1 per day.**
   - **4mg: #1 per day.**
   - **6mg: #2 per day.**
   - **8mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DAPRODUSTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DAPRODUSTAT (Jesduvroq)** requires the following rule(s) be met for approval:

A. You have anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
B. You are 18 years of age or older
C. You have been receiving dialysis (process of removing excess water, toxins from the blood) for at least 4 months
D. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
E. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of less than 60 mL/min/1.73m(2), confirming stage 3, 4, or 5 chronic (long-term) kidney disease (CKD)
F. You will NOT use Jesduvroq concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Vafseo [vadadustat]) OR erythropoiesis-stimulating agents (ESAs) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])
G. If you are NOT currently being treated with an erythropoiesis-stimulating agent (ESA: medications used to treat anemia such as Epogen, Procrit), approval also requires:
    1. You have a hemoglobin level (a type of blood test) of less than 11 g/dL
H. If you are currently being treated with an erythropoiesis-stimulating agent (ESA: medications used to treat anemia such as Epogen, Procrit), approval also requires:
    1. You have a hemoglobin level (a type of blood test) of less than 12 g/dL
    2. You will discontinue erythropoiesis-stimulating agent (ESA) therapy (such as Epogen [epoetin alfa], Procrit [epoetin alfa]) before starting Jesduvroq

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DAPRODUSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   - The patient has a hemoglobin level of at least 10 g/dL OR the patient's hemoglobin level has increased by at least 2 g/dL from their baseline level
   - Jesduvroq will NOT be used concurrently with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (e.g., Vafseo [vadadustat]) OR erythropoiesis-stimulating agents (ESAs) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **1mg: #1 per day.**
   - **2mg: #1 per day.**
   - **4mg: #1 per day.**
   - **6mg: #2 per day.**
   - **8mg: #3 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAPRODUSTAT (Jesduvroq)** requires the following rule(s) be met for renewal:
   A. You have anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
   B. You have a hemoglobin level (a type of blood test) of at least 10 g/dL OR your hemoglobin level has increased by at least 2 g/dL from your baseline level (before treatment)
   C. You will NOT use Jesduvroq concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Vafseo [vadadustat]) OR erythropoiesis-stimulating agents (ESAs) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DAPRODUSTAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jesduvroq.

REFERENCES

Jesduvroq [Prescribing Information]. Durham, NC: GlaxoSmithKline; August 2023.

Created: 09/23
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARATUMUMAB	DARZALEX	42814		GPI-10 (2135402700)	

GUIDELINES FOR USE

1. Does the patient have a newly diagnosed multiple myeloma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is ineligible for autologous stem cell transplant
   - The requested medication will be used in combination with lenalidomide and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory multiple myeloma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least one prior therapy
   - The requested medication will be used in combination with lenalidomide and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a newly diagnosed multiple myeloma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is ineligible for autologous stem cell transplant
   - The requested medication will be used in combination with bortezomib (Velcade), melphalan and prednisone [VMP]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a newly diagnosed multiple myeloma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is eligible for autologous stem cell transplant
   - The requested medication will be used in combination with bortezomib (Velcade), thalidomide and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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DARATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
   The patient is 18 years of age or older
   - The patient has received at least one prior therapy
   - The requested medication will be used in combination with bortezomib and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have a diagnosis of relapsed or refractory multiple myeloma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received one to three prior lines of therapy
   - The requested medication will be used in combination with carfilzomib and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI) [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)]
   - The requested medication will be used in combination with pomalidomide and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

8. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least three prior therapies, including a proteasome inhibitor (PI) [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)] **AND** an immunomodulatory agent [e.g., lenalidomide (Revlimid), pomalidomide (Pomalyst), thalidomide (Thalomid)]
   - The requested medication will be used as monotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

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DARATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is refractory to both a proteasome inhibitor (PI) [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), or ixazomib (Ninlaro)] **AND** an immunomodulatory agent [e.g., lenalidomide (Revlimid), pomalidomide (Pomalyst), or thalidomide (Thalomid)]
   - The requested medication will be used as monotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DARATUMUMAB (Darzalex)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (plasma cell cancer)
   B. You are 18 years of age or older
   C. You meet **ONE** of the following criteria:
      1. You have newly diagnosed multiple myeloma and are not eligible for autologous stem cell transplant (cells from your own body) and will receive daratumumab in combination with lenalidomide and dexamethasone
      2. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) and received at least one prior therapy **AND** will receive daratumumab in combination with lenalidomide and dexamethasone
      3. You are newly diagnosed with multiple myeloma, not eligible for autologous stem cell transplant (cells from your own body), **AND** will receive daratumumab in combination with bortezomib, melphalan and prednisone
      4. You are newly diagnosed with multiple myeloma, are eligible for autologous stem cell transplant (cells from your own body), **AND** will receive daratumumab in combination with bortezomib, thalidomide and prednisone
      5. You have received at least one prior therapy **AND** will receive daratumumab in combination with bortezomib and dexamethasone
      6. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) and received one to three prior lines of therapy **AND** will receive daratumumab in combination with carfilzomib and dexamethasone
      7. You have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI: class of drug for myeloma cancer) **AND** will receive daratumumab in combination with pomalidomide and dexamethasone

   (Denial text continued on next page)

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DARATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

8. You have received at least three prior lines of therapy, including a proteasome inhibitor (class of drug for myeloma) and an immunomodulatory agent (drug that changes the immune response or the functioning of the immune system) **AND** you will receive daratumumab as monotherapy (single drug to treat condition)
9. You are refractory (resistant) to both a proteasome inhibitor and an immunomodulatory agent **AND** will receive daratumumab as monotherapy

Note: Proteasome inhibitors examples include: bortezomib, carfilzomib, or ixazomib and Immunomodulatory agent examples include: lenalidomide, pomalidomide, or thalidomide.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Darzalex.

REFERENCES

Darzalex [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 12/15
Client Approval: 03/21
P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB-HYALURONIDASE-FIHJ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARATUMUMAB-HYALURONIDASE-FIHJ	DARZALEX FASPRO	46509		GPI-10 (2199000215)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #9.

2. Is the patient newly diagnosed?

   If yes, continue to #3.
   If no, continue to #5.

3. Is the patient ineligible for an autologous stem cell transplant and meets **ONE** of the following criteria?
   - Darzalex Faspro will be used in combination with bortezomib (Velcade), melphalan, and prednisone
   - Darzalex Faspro will be used in combination with lenalidomide (Revlimid) and dexamethasone
   - Darzalex Faspro will be used in combination with bortezomib (Velcade), lenalidomide (Revlimid) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient eligible for an autologous stem cell transplant and meets **ONE** of the following criteria?
   - Darzalex Faspro will be used in combination with bortezomib (Velcade), lenalidomide (Revlimid), and dexamethasone for induction and consolidation treatment
   - Darzalex Faspro will be used in combination with bortezomib (Velcade), thalidomide (Thalomid), and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

5. Is the patient's disease relapsed or refractory and the patient meets **ONE** of the following criteria?
   - The patient has received at least one prior therapy, AND Darzalex Faspro will be used in combination with lenalidomide (Revlimid) and dexamethasone
   - The patient has received one to three prior lines of therapy, AND Darzalex Faspro will be used in combination with carfilzomib (Kyprolis) and dexamethasone
   - The patient has received at least one prior line of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), AND Darzalex Faspro will be used in combination with Tecvayli (teclistamab-cqyv)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Has the patient received at least one prior therapy **AND** meets the following criterion?
   - Darzalex Faspro will be used in combination with bortezomib (Velcade) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Has the patient received at least one prior line of therapy, including lenalidomide (Revlimid) and a proteasome inhibitor [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)] **AND** meets the following criterion?
   - Darzalex Faspro will be used in combination with pomalidomide (Pomalyst) and dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

8. Will Darzalex Faspro be used as monotherapy and the patient meets **ONE** of the following criteria?
   - The patient has received at least three prior lines of therapy, including a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) and an immunomodulatory agent (e.g., lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
   - The patient is refractory to both a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) and an immunomodulatory agent (e.g., lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
   - The patient has high-risk smoldering multiple myeloma

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

9. Does the patient have newly diagnosed light chain (AL) amyloidosis (ICD-10 E85.81) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Darzalex Faspro will be used in combination with bortezomib (Velcade), cyclophosphamide, and dexamethasone

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DARATUMUMAB-HYALURONIDASE-FIHJ (Darzalex Faspro)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Multiple myeloma (a type of blood cancer)
   2. Newly diagnosed light chain (AL) amyloidosis (a buildup of proteins in the tissues causing organ dysfunction)

B. You are 18 years of age or older

C. If you have multiple myeloma, approval also requires ONE of the following:

   1. Your disease is newly diagnosed and you meet ONE of the following:
      a. You are NOT eligible for an autologous stem cell transplant (a type of procedure to replace damaged bone marrow with cells from your own body) and you meet ONE of the following:
         i. You will use Darzalex Faspro in combination with bortezomib (Velcade), melphalan, and prednisone
         ii. You will use Darzalex Faspro in combination with lenalidomide (Revlimid) and dexamethasone
         iii. You will use Darzalex Faspro in combination with bortezomib (Velcade), lenalidomide (Revlimid) and dexamethasone
      b. You are eligible for an autologous stem cell transplant (a type of procedure to replace damaged bone marrow with cells from your own body) and you meet ONE of the following:
         i. You will use Darzalex Faspro in combination with bortezomib (Velcade), lenalidomide (Revlimid), and dexamethasone for induction (start of treatment) and consolidation treatment (treatment following initial therapy)
         ii. You will use Darzalex Faspro in combination with bortezomib (Velcade), thalidomide (Thalomid), and dexamethasone

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GUIDELINES FOR USE (CONTINUED)

2. Your disease is relapsed or refractory (disease has returned or did not respond to treatment) and you meet ONE of the following:
   a. You have received at least one prior therapy AND you will use Darzalex Faspro in combination with lenalidomide (Revlimid) and dexamethasone
   b. You have received one to three prior lines of therapy AND you will use Darzalex Faspro in combination with carfilzomib (Kyprolis) and dexamethasone
   c. You have received at least one prior line of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), AND Darzalex Faspro will be used in combination with Tecvayli (teclistamab-cqyv)
3. You have received at least one prior therapy AND you will use Darzalex Faspro in combination with bortezomib (Velcade) and dexamethasone
4. You have received at least one prior line of therapy, including lenalidomide (Revlimid) and a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]), AND you will use Darzalex Faspro in combination with pomalidomide (Pomalyst) and dexamethasone
5. You will use Darzalex Faspro as monotherapy (one drug treatment) and meet ONE of the following:
   a. You have received at least three prior lines of therapy, including a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) AND an immunomodulatory agent (such as lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
   b. You are refractory (disease did not respond to treatment) to both a proteasome inhibitor (such as bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]) AND an immunomodulatory agent (such as lenalidomide [Revlimid], pomalidomide [Pomalyst], thalidomide [Thalomid])
   c. You have high-risk smoldering multiple myeloma (the stage before active disease)

D. If you have newly diagnosed light chain amyloidosis, approval also requires:

1. You will use Darzalex Faspro in combination with bortezomib (Velcade), cyclophosphamide, and dexamethasone

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Darzalex Faspro and Tecvayli.

REFERENCES

Darzalex Faspro [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; February 2026.
Tecvayli [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc., March 2026.

Created: 08/20
Effective: 03/18/26 Client Approval: 03/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DARAXONRASIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARAXONRASIB	RASONQUE	51500		GPI-10 (2153432000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic pancreatic adenocarcinoma (ICD-10 Group C25) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an oncologist
   - The patient has received at least one prior systemic therapy OR is not a candidate for a multiagent systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: Our guideline named **DARAXONRASIB (Rasonque)** requires the following rule(s) be met for approval:
   A. You have metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
   B. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   C. You have received at least one prior systemic therapy (treatment that targets the entire body) OR you are not a candidate for a multiagent systemic therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rasonque.

REFERENCES

Rasonque [Prescribing Information]. Redwood City, CA: Revolution Medicines, Inc.; August 2026.

Created: 09/26
Effective: 09/09/26 Client Approval: 09/26 DMC Approval: 09/09/26

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DARBEPOETIN ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARBEPOETIN ALFA IN POLYSORBAT	ARANESP	22890		GPI-10 (8240101510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL
   - Aranesp will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #2.

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DARBEPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 11g/dL OR the patient's hemoglobin level has decreased at least 2g/dL below baseline level
   - Aranesp will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #3.

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DARBEPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL
   - The patient had a trial of or contraindication to ribavirin dose reduction
   - Aranesp will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DARBEPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
   2. Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
   3. Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. If you have anemia due to chronic kidney disease, approval also requires:
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level (a type of blood test) is less than 10g/dL
   3. You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

C. If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level (a type of blood test) is less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level
   3. You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

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DARBEPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

D. If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:

1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
2. Your hemoglobin level (a type of blood test) is less than 10g/dL
3. You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
4. You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DARBEPOETIN ALFA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   - Aranesp will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta] OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL if not on dialysis
   - The patient's hemoglobin level is less than 11g/dL if on dialysis
   - The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions
   - The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #3.

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

3. Is the request for a pediatric patient (less than 18 years of age) and the patient meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient's hemoglobin level has approached or exceeds 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL
   - Aranesp will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta] OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, continue to #5.

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL
   - Aranesp will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta] OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **25mcg/mL vial: #4mL per 28 days.**
   - **40mcg/mL vial: #4mL per 28 days.**
   - **60mcg/mL vial: #4mL per 28 days.**
   - **100mcg/mL vial: #4mL per 28 days.**
   - **200mcg/mL vial: #4mL per 28 days.**
   - **10mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **25mcg/0.42mL syringe: #1.68mL per 28 days.**
   - **40mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **60mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **100mcg/0.5mL syringe: #2mL per 28 days.**
   - **150mcg/0.3mL syringe: #1.2mL per 28 days.**
   - **200mcg/0.4mL syringe: #1.6mL per 28 days.**
   - **300mcg/0.6mL syringe: #2.4mL per 28 days.**
   - **500mcg/mL syringe: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DARBEPOETIN ALFA (Aranesp)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
   2. Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
   3. Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. If you have anemia due to chronic kidney disease, renewal also requires:
   1. You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])
   2. If you are an adult (you are 18 years of age or older), renewal also requires ONE of the following:
      a. Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
      b. Your hemoglobin level (a type of blood test) is less than 11g/dL if you are on dialysis (process of removing excess water, toxins from the blood)
      c. Your hemoglobin level (a type of blood test) has reached 10g/dL (if you are not on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
      d. Your hemoglobin level (a type of blood test) has reached 11g/dL (if you are on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
   3. If you are a pediatric patient (you are less than 18 years of age), renewal also requires ONE of the following:
      a. Your hemoglobin level (a type of blood test) is less than 10g/dL
      b. Your hemoglobin level (a type of blood test) has approached or exceeds 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

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DARBEPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

C. If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
1. Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
2. You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

D. If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
1. Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
2. You will NOT use Aranesp concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Epogen [epoetin alfa], Procrit [epoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Aranesp.

REFERENCES
Aranesp [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; December 2024.

Created: 02/11
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAROLUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DAROLUTAMIDE	NUBEQA	45909		GPI-10 (2140242500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC) (ICD-10 Z19.2, C61) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Nubeqa will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DAROLUTAMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-metastatic castration resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
   2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

B. If you have non-metastatic castration resistant prostate cancer, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have received a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      c. Nubeqa will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

C. If you have metastatic castration-sensitive prostate cancer, approval also requires ONE of the following:
   1. You have received a bilateral orchiectomy (both testicles have been surgically removed)
   2. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
   3. Nubeqa will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nubeqa.

REFERENCES

Nubeqa [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; June 2025.

Created: 11/19
Effective: 11/10/25 Client Approval: 10/25 P&T Approval: 10/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DASATINIB-PHYRAGO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DASATINIB	PHYRAGO	33855		GPI-10 (2153182000)	BRAND = PHYRAGO

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) **AND** meet the following criterion?
   - The patient has a contraindication to generic dasatinib

   If yes, continue to #2.
   If no, continue to #4.

2. Is the Ph+ CML in chronic phase (CP) and the patient meets **ONE** of the following criteria?
   - The patient is 18 years of age or older AND is newly diagnosed (e.g., starting or previously started treatment with Phyrago at the time of diagnosis)
   - The patient is between 1 and 17 years of age

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, continue to #3.

3. Is the Ph+ CML in chronic, accelerated, myeloid or lymphoid blast phase, and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
   - The patient had a mutational analysis prior to initiation AND Phyrago is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DASATINIB-PHYRAGO

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0) **AND** meet the following criterion?
   - The patient has a contraindication to generic dasatinib

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the patient 18 years of age or older **AND** has a resistance or intolerance to prior therapy (e.g., imatinib [Gleevec], nilotinib [Tasigna])?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, continue to #6.

6. Is the patient between 1 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is newly diagnosed (e.g., starting or previously started treatment with Phyrago at the time of diagnosis)
   - Phyrago will be used in combination with chemotherapy

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DASATINIB (Phyrago)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer)
      2. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cell cancer)

   (Denial text continued on the next page)

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DASATINIB

GUIDELINES FOR USE (CONTINUED)

B. If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires:
1. You have a contraindication to (harmful for you to use) generic dasatinib
2. You meet ONE of the following:
   a. You are 18 years of age or older AND you are newly diagnosed (such as you are starting or previously started treatment with Phyrago at the time your condition was identified)
   b. You are between 1 and 17 years of age

C. If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, myeloid or lymphoid blast phase, approval also requires:
1. You are 18 years of age or older
2. You have a contraindication to (harmful for you to use) generic dasatinib
3. You have resistance (medication no longer works) or intolerance (side effect) to prior therapy including imatinib (Gleevec)
4. You had a mutational analysis (a type of lab test) prior to the start of therapy AND Phyrago is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

D. If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires:
1. You have a contraindication to (harmful for you to use) generic dasatinib
2. You meet ONE of the following:
   a. You are 18 years of age or older AND have a resistance (medication no longer works) or intolerance (side effect) to prior therapy (such as imatinib [Gleevec], nilotinib [Tasigna])
   b. You are between 1 and 17 years of age; you are newly diagnosed (such as you are starting or previously started treatment with Phyrago at the time your condition was identified); AND you will be using Phyrago in combination with chemotherapy (medications used to treat cancer)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Phyrago.

REFERENCES
Phyrago [Prescribing information]. San Jose, CA: Handa Therapeutics, LLC; August 2025.

Created: 09/25
Effective: 10/01/25 Client Approval: 09/25 P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DASATINIB-SPRYCEL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DASATINIB	SPRYCEL, DASATINIB	33855		GPI-10 (2153182000)	BRAND ≠ PHYRAGO

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the Ph+ CML in chronic phase (CP) and the patient meets **ONE** of the following criteria?
   - The patient is 18 years of age or older AND is newly diagnosed (e.g., starting or previously started treatment with the requested medication at the time of diagnosis)
   - The patient is between 1 and 17 years of age

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, continue to #3.

3. Is the Ph+ CML in chronic, accelerated, myeloid or lymphoid blast phase, and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
   - The patient had a mutational analysis prior to initiation AND the requested medication is appropriate based on the NCCN guideline table for treatment recommendations based on BCR- ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DASATINIB-SPRYCEL

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the patient 18 years of age or older **AND** has a resistance or intolerance to prior therapy (e.g., imatinib [Gleevec], nilotinib [Tasigna])?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, continue to #6.

6. Is the patient between 1 and 17 years of age and meets **ALL** of the following criteria?
   - The patient is newly diagnosed (e.g., starting or previously started treatment with the requested medication at the time of diagnosis)
   - The requested medication will be used in combination with chemotherapy

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **20mg: #3 per day.**
   - **50mg, 70mg, 80mg, 100mg, 140mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DASATINIB (Sprycel)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer)
      2. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cell cancer)

   (Denial text continued on the next page)

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GUIDELINES FOR USE (CONTINUED)

B. If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires ONE of the following:
1. You are 18 years of age or older AND you are newly diagnosed (such as you are starting or previously started treatment with the requested medication at the time your condition was identified)
2. You are between 1 and 17 years of age

C. If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, myeloid or lymphoid blast phase, approval also requires:
1. You are 18 years of age or older
2. You have resistance (medication no longer works) or intolerance (side effect) to prior therapy including imatinib (Gleevec)
3. You had a mutational analysis (a type of lab test) prior to the start of therapy AND the requested medication is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

D. If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:
1. You are 18 years of age or older AND have a resistance (medication no longer works) or intolerance (side effect) to prior therapy (such as imatinib [Gleevec] or nilotinib [Tasigna])
2. You are between 1 and 17 years of age; you are newly diagnosed (such as you are starting or previously started treatment with the requested medication at the time your condition was identified); AND you will be using the requested medication in combination with chemotherapy (medications used to treat cancer)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sprycel.

REFERENCES

Sprycel [Prescribing information]. Princeton, NJ: Bristol-Myers Squibb; July 2024.

Created: 05/12
Effective: 10/01/25 Client Approval: 09/25 P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DATOPOTAMAB DERUXTECAN-DLNK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DATOPOTAMAB DERUXTECAN-DLNK	DATROWAY	50179		GPI-10 (2155102020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic breast cancer (ICD-10 Group C50) and meet **ONE** of the following criteria?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+, or IHC 2+/ISH-) AND the patient has received prior endocrine-based therapy (e.g., letrozole, anastrozole, tamoxifen) and chemotherapy for unresectable or metastatic disease
   - The patient's cancer is triple-negative (TNBC) AND the patient is not a candidate for PD-1/PD-L1 inhibitor therapy (e.g., Keytruda [pembrolizumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is epidermal growth factor receptor (EGFR)-mutated
   - The patient has received prior EGFR-directed therapy (e.g., Tagrisso [osimertinib]) and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DATOPOTAMAB DERUXTECAN-DLNK (Datroway)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Unresectable or metastatic breast cancer (a type of breast cancer that cannot be removed by surgery or has spread to other parts of the body)
      2. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)

   (Denial text continued on next page)

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DATOPOTAMAB DERUXTECAN-DLNK

GUIDELINES FOR USE (CONTINUED)

B. If you have unresectable or metastatic breast cancer, approval also requires ONE of the following:
1. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative (IHC 0, IHC 1+, or IHC 2+/ISH- [type of lab test]) AND you had prior endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen) and chemotherapy (medications used to treat cancer) for unresectable or metastatic disease
2. Your cancer is triple-negative (TNBC: a type of breast cancer) AND you are not a candidate for PD-1 (programmed cell death 1: a type of protein)/PD-L1 (programmed death-ligand 1: a type of protein) inhibitor therapy (such as Keytruda [pembrolizumab])

C. If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your cancer is epidermal growth factor receptor (EGFR: a type of protein)-mutated (abnormal change in a type of gene)
3. You have received prior epidermal growth factor receptor (EGFR: a type of protein)-directed therapy (such as Tagrisso [osimertinib]) and platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Datroway.

REFERENCES

Datroway [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; May 2026.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAUNORUBICIN/CYTARABINE LIPOSOME (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DAUNORUBICIN/ CYTARABINE LIPOSOME	VYXEOS	44461		GPI-10 (2199000220)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient has newly diagnosed therapy-related acute myeloid leukemia (t-AML) **OR** AML with myelodysplasia-related changes (AML-MRC)
   - The patient is 1 year of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAUNORUBICIN/CYTARABINE LIPOSOME (Vyxeos)** requires the following rule(s) be met for approval:
   A. You have a new diagnosis of therapy-related acute myeloid leukemia (type of white blood cell cancer) OR acute myeloid leukemia with myelodysplasia-related changes (type of blood and bone marrow cancer that affects production of blood cells)
   B. You are 1 year of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyxeos.

REFERENCES
Vyxeos [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc. March 2021.

Library	Commercial	NSA
No	No	Yes

Part D Effective: N/A
Commercial Effective: 05/01/21
Created: 08/17
Client Approval: 04/21
P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAXIBOTULINUMTOXINA-LANM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DAXIBOTULINUMTOXINA-LANM	DAXXIFY	48287		GPI-10 (7440002015)	

GUIDELINES FOR USE

1. Is the request for a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines) (ICD-10 L98.8)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) (ICD-10 G24.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 vials every 3 months.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DAXIBOTULINUMTOXINA-LANM (Daxxify)** requires the following rule(s) be met for approval:
   A. You have cervical dystonia (a type of muscle condition)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

   NOTE: This medication will NOT be approved for a cosmetic indication (for example wrinkles - glabellar lines, lateral canthal lines, forehead lines).

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DAXIBOTULINUMTOXINA-LANM

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Daxxify.

REFERENCES
Daxxify [Prescribing Information]. Newark, CA: Revance Therapeutics, Inc.; November 2023.

Created: 11/23
Effective: 10/04/25 Client Approval: 09/25 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DECITABINE/CEDAZURIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DECITABINE/ CEDAZURIDINE	INQOVI	46686		GPI-10 (2199000225)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of myelodysplastic syndromes (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an International Prognostic Scoring System group of intermediate-1, intermediate-2, or high-risk

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic myelomonocytic leukemia (CMML) (ICD-10 C93.1) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - The patient is newly diagnosed (e.g., starting or previously started Inqovi treatment at the time of diagnosis)
   - Inqovi will be used in combination with Venclexta (venetoclax)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DECITABINE/CEDAZURIDINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DECITABINE/CEDAZURIDINE (Inqovi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Myelodysplastic syndromes (MDS: a type of blood cancer)
   2. Chronic myelomonocytic leukemia (CMML: a type of blood cancer)
   3. Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)

B. If you have myelodysplastic syndromes, approval also requires:
   1. You are 18 years of age or older
   2. You have an International Prognostic Scoring System (a tool for evaluating severity of myelodysplastic syndrome) group of intermediate-1, intermediate-2, or high-risk

C. If you have chronic myelomonocytic leukemia, approval also requires:
   1. You are 18 years of age or older

D. If you have acute myeloid leukemia, approval also requires:
   1. You are newly diagnosed (such as you are starting or previously started Inqovi treatment at the time your condition was identified)
   2. Inqovi will be used in combination with Venclexta (venetoclax)
   3. You meet ONE of the following:
      a. You are 75 years of age or older
      b. You are 18 years of age or older with comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of therapy to treat cancer)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inqovi.

REFERENCES

Inqovi [Prescribing Information]. Pleasanton, CA: Astex Pharmaceuticals, Inc.; May 2026.

Created: 10/20
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFERASIROX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFERASIROX	EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX	33337		GPI-10 (9310002500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic iron overload due to blood transfusions (ICD-10 E83.111) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or hematologist/oncologist
   - The patient's serum ferritin levels are consistently greater than 1000 mcg/L (at least two lab values in the previous 3 months)

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of thalassemia (ICD-10 Group D56) and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient has chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT)
   - Therapy is prescribed by or in consultation with a hematologist or hematologist/oncologist
   - The patient's serum ferritin levels are consistently greater than 300 mcg/L (at least two lab values in the previous 3 months)
   - The patient's liver iron concentration (LIC) is at least 5 mg Fe/g liver dry weight

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for Exjade (deferasirox) tablet for oral suspension or Jadenu (deferasirox) tablets?

   If yes, **approve Exjade or Jadenu tablets for all strengths of the requested drug for 6 months by GPID or GPI-14.**

   If no, continue to #4.

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DEFERASIROX

INITIAL CRITERIA (CONTINUED)

4. Is the request for Jadenu (deferasirox) sprinkle packets **AND** the patient meets the following criterion?
   - The patient has tried one preferred agent: generic deferasirox tablet for oral suspension OR deferasirox tablet

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFERASIROX (Exjade, Jadenu, Jadenu Sprinkle)** requires the following rule(s) be met for approval:

   A. You have one of the following:
      1. Chronic iron overload (too much iron in the body) due to blood transfusions (blood transfers)
      2. Thalassemia (a type of blood disorder)

   B. If you have chronic iron overload due to blood transfusions, approval also requires:
      1. You are 2 years of age or older
      2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of blood/cancer doctor)
      3. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 1000 mcg/L (at least two lab values in the previous 3 months)

   C. If you have thalassemia, approval also requires:
      1. You are 10 years of age or older
      2. You have chronic iron overload (too much iron in the body) resulting from non-transfusion dependent thalassemia (NTDT: type of blood disorder that does not require regular blood transfusion)
      3. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of blood/cancer doctor)
      4. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300 mcg/L (at least two lab values in the previous 3 months)
      5. Your liver iron concentration (LIC) is at least 5 mg of iron per gram (Fe/g) of liver dry weight

   D. If your request is for Jadenu sprinkle packets, approval also requires:
      1. You have tried one preferred medication: generic deferasirox tablet for oral suspension or deferasirox tablet

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFERASIROX

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic iron overload due to blood transfusions (ICD-10 E83.111) **AND** meet the following criterion?
   - The patient's serum ferritin levels are consistently greater than 500 mcg/L (at least two lab values in the previous 3 months)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of thalassemia (ICD-10 Group D56) and meet **ONE** of the following criteria?
   - The patient's serum ferritin levels are consistently greater than 300 mcg/L (at least two lab values in the previous 3 months)
   - The patient's liver iron concentration (LIC) is at least 3 mg Fe/g liver dry weight (*Liver iron concentration supersedes serum ferritin level when both measurements are available*)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFERASIROX (Exjade, Jadenu, Jadenu Sprinkle)** requires the following rule(s) be met for renewal:
   A. You have one of the following:
      1. Chronic iron overload (too much iron in the body) due to blood transfusions (blood transfers)
      2. Thalassemia (a type of blood disorder)

   B. If you have chronic Iron overload due to blood transfusions, renewal also requires:
      1. Your serum ferritin levels (type of lab test) are regularly greater than 500 mcg/L (at least two lab values in the previous 3 months)

   C. If you have thalassemia, renewal also requires ONE of the following:
      1. Your serum ferritin levels (type of lab test) are regularly greater than 300 mcg/L (at least two lab values in the previous 3 months)
      2. Your liver iron concentration (LIC) is at least 3 mg of iron per gram (Fe/g) of liver dry weight

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFERASIROX

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exjade and Jadenu.

REFERENCES

Jadenu [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

Exjade [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

Created: 08/17
Effective: 05/28/26 Client Approval: 05/26 P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFERIPRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFERIPRONE	FERRIPROX, DEFERIPRONE	18544		GPI-10 (9310002800)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Thalassemia (ICD-10 Group D56)
   - Sickle cell disease (ICD-10 Group D57)
   - Anemia (ICD-10 Group D64)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has transfusional iron overload
   - Therapy is prescribed by or in consultation with a hematologist or hematologist/oncologist
   - The patient had a trial of or contraindication to at least ONE clinical standard of care agent: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following?
   - The patient is experiencing intolerable toxicities or clinically significant adverse effects, or has a contraindication to current chelators: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
   - The patient's current chelation therapy (i.e., Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is inadequate

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFERIPRONE

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The request is for Ferriprox (deferiprone) tablets AND the patient is 8 years of age or older
   - The request is for Ferriprox oral solution AND the patient is 3 years of age or older

   If yes, **approve for 6 months for all strengths of the requested formulation by GPID or GPI-14.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Thalassemia (a type of blood disorder)
      2. Sickle cell disease (a type of blood disorder)
      3. Anemia (a type of blood disorder)

   B. You have transfusional iron overload (too much iron in the body caused by blood transfusions)

   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of blood/cancer doctor)

   D. You have tried or have a contraindication to (harmful for you to use) at least ONE clinical standard of care medication: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)

   E. You meet ONE of the following:
      1. You are experiencing intolerable toxicities or clinically significant adverse effects, or have a contraindication to (harmful for you to use) current chelators (drugs that bind to iron): Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
      2. Current chelation therapy (treatment that lowers iron levels) with Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough

   F. If the request is for Ferriprox (deferiprone) tablets, approval also requires:
      1. You are 8 years of age or older

   G. If the request is for Ferriprox oral solution, approval also requires:
      1. You are 3 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFERIPRONE

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Thalassemia (ICD-10 Group D56)
   - Sickle cell disease (ICD-10 Group D57)
   - Anemia (ICD-10 Group D64)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet the following criterion?
   - The patient has serum ferritin levels consistently greater than 500 mcg/L (at least two lab values in the previous 3 months)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The request is for Ferriprox (deferiprone) tablets AND the patient is 8 years of age or older
   - The request is for Ferriprox oral solution AND the patient is 3 years of age or older

   If yes, **approve for 12 months for all strengths of the requested formulation by GPID or GPI-14.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFERIPRONE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Thalassemia (a type of blood disorder)
   2. Sickle cell disease (a type of blood disorder)
   3. Anemia (a type of blood disorder)

B. Your serum ferritin levels (amount of iron-containing blood cell proteins) are consistently above 500 mcg/L (at least two lab values in the previous 3 months)

C. If the request is for Ferriprox (deferiprone) tablets, approval also requires:
   1. You are 8 years of age or older

D. If the request is for Ferriprox oral solution, approval also requires:
   1. You are 3 years of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ferriprox.

REFERENCES

Ferriprox [Prescribing Information]. Cary, NC: Chiesi USA, Inc.; July 2023.

Created: 08/17
Effective: 05/28/26 Client Approval: 05/26 P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFEROXAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFEROXAMINE MESYLATE	DESFERAL MESYLATE, DEFEROXAMINE MESYLATE	01104		GPI-10 (9300002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of transfusional iron overload with chronic anemia and meet **ALL** of the following criteria?

- The patient is 3 years of age or older
- Therapy is prescribed by or in consultation with a hematologist or hematologist/oncologist
- The patient has serum ferritin levels that are consistently greater than 1000 mcg/L (at least two lab values in the previous 3 months)

If yes, **approve for 6 months by HICL or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for approval:

A. You have transfusional iron overload (too much iron in the body caused by blood transfusions) with chronic (long-term) anemia (a type of blood disorder)
B. You are 3 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or hematologist/oncologist (a type of blood/cancer doctor)
D. Your serum ferritin levels (type of lab test) are consistently greater than 1000 mcg/L (at least two lab values in the previous 3 months)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFEROXAMINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of transfusional iron overload with chronic anemia **AND** meet the following criterion?
   - The patient has serum ferritin levels that are consistently greater than 500 mcg/L (at least two lab values in the previous 3 months)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for renewal:
   A. You have transfusional iron overload (too much iron in the body caused by blood transfusions) with chronic (long-term) anemia (type of blood disorder)
   B. Your serum ferritin levels (type of lab test) are consistently greater than 500 mcg/L (at least two lab values in the previous 3 months)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Desferal.

REFERENCES

Desferal [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022.

Created: 08/17
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/17

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEFLAZACORT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEFLAZACORT	EMFLAZA, DEFLAZACORT, JAYTHARI, KYMBEE, PYQUVI	11668		GPI-10 (2210001700)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   - The patient's diagnosis of DMD is confirmed by genetic testing

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient tried prednisone or prednisolone for at least 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFLAZACORT

INITIAL CRITERIA (CONTINUED)

3. Did the patient experience a lack of efficacy with prednisone or prednisolone and meets **ALL** of the following criteria?
   - The patient is not in Stage 1 of the disease (the pre-symptomatic phase)
   - Steroid myopathy has been ruled out
   - The patient has experienced deterioration in ambulation, functional status, or pulmonary function while on prednisone or prednisolone that is consistent with advancing disease (stage 2 or higher) and assessed using standard measures over time (e.g., 6-minute walking distance [6MWD], time to ascend/descend 4 stairs, rise from floor time [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA], Physician Global Assessment [PGA], pulmonary function tests [FVC, PFTs], upper limb strength [propelling a wheelchair 30 feet])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **6mg tablet: #2 per day.**
   - **18mg tablet: #1 per day.**
   - **30mg tablet: #2 per day.**
   - **36mg tablet: #2 per day.**
   - **22.75mg/mL oral suspension: #1.3mL per day.**

   If no, continue to #4.

4. Did the patient experience a significant adverse effect (e.g., weight gain) on prednisone or prednisolone that is negatively impacting a comorbid condition (e.g., diabetes)?

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **6mg tablet: #2 per day.**
   - **18mg tablet: #1 per day.**
   - **30mg tablet: #2 per day.**
   - **36mg tablet: #2 per day.**
   - **22.75mg/mL oral suspension: #1.3mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEFLAZACORT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFLAZACORT (Emflaza, Jaythari, Kymbee, Pyquvi)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You are 2 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD: a type of muscle disorder) at a DMD treatment center
D. Your diagnosis of Duchenne muscular dystrophy (DMD: a type of muscle disorder) is confirmed by genetic testing
E. You have tried prednisone or prednisolone for at least 6 months
F. You meet ONE of the following:
    1. Prednisone or prednisolone did not work for you, and you meet **ALL** of the following:
        a. You are not in Stage 1 of the disease (the pre-symptomatic phase)
        b. There is no steroid myopathy (muscle disease due to steroid use)
        c. You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function, while treated with prednisone or prednisolone, that is consistent with advancing disease (stage 2 or higher) and that is assessed by standard measures over time (such as the 6-minute walking distance [6MWD], time to go up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy], Physician Global Assessment [PGA: an evaluation by a physician], pulmonary function [forced vital capacity, lung function tests], upper limb strength [moving a wheelchair 30 feet])
    2. You have experienced a significant adverse effect (such as weight gain) on prednisone or prednisolone that is negatively impacting a co-existing comorbid condition (such as diabetes [a disorder with high blood sugar])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEFLAZACORT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently ambulatory **AND** meets the following criterion?
   - The patient has shown function or improvement since being on the requested medication, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], time to ascend/descend 4 stairs, rise from floor time [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA], Physician Global Assessment [PGA])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **6mg tablet: #2 per day.**
   - **18mg tablet: #1 per day.**
   - **30mg tablet: #2 per day.**
   - **36mg tablet: #2 per day.**
   - **22.75mg/mL oral suspension: #1.3mL per day.**

   If no, continue to #3.

3. Is the patient currently non-ambulatory **AND** meets the following criterion?
   - The patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength since being on the requested medication, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength measures [propelling a wheelchair 30 feet], Physician Global Assessment [PGA])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **6mg tablet: #2 per day.**
   - **18mg tablet: #1 per day.**
   - **30mg tablet: #2 per day.**
   - **36mg tablet: #2 per day.**
   - **22.75mg/mL oral suspension: #1.3mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFLAZACORT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEFLAZACORT (Emflaza, Jaythari, Kymbee, Pyquvi)** requires the following rule(s) be met for renewal:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)

B. If you are currently ambulatory (can walk), approval also requires:

1. You have shown function or improvement since being on the requested medication as measured by a standard set of ambulatory or functional status measures (such as the 6-minute walking distance [6MWD], time to go up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy], Physician Global Assessment [PGA: an evaluation by a physician])

C. If you are currently non-ambulatory (cannot walk), approval also requires:

1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength since being on the requested medication as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength measures [moving in a wheelchair 30 feet], Physician Global Assessment [PGA: an evaluation by a physician])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emflaza, Jaythari, Kymbee, and Pyquvi.

REFERENCES

Emflaza [Prescribing Information]. Warren, NJ: PTC Therapeutics, Inc.; June 2024.
Jaythari [Prescribing Information]. Pennington, NJ: Zydus Pharmaceuticals (USA), Inc.; May 2025.
Kymbee [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; July 2025.
Pyquvi [Prescribing Information]. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; February 2025.

Created: 02/17
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DELAFLOXACIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DELAFLOXACIN MEGLUMINE	BAXDELA		43532	GPI-14 (05000025100320)	

GUIDELINES FOR USE

1. Is therapy prescribed by or in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve for 1 month as follows:**
   - **Acute bacterial skin or skin structure infection (ABSSSI): Approve the 450mg tablet by GPID or GPI-14 with a quantity limit of #28 per 14 days for 1 fill.**
   - **Community-acquired bacterial pneumonia (CABP): Approve the 450mg tablet by GPID or GPI-14 with a quantity limit of #20 per 10 days for 1 fill.**
   - **Other indications: Approve the 450mg tablet by GPID or GPI-14 with a quantity limit of #28 per 14 days for 1 fill.**

   If no, continue to #2.

2. Does the patient have a diagnosis of an acute bacterial skin or skin structure infection (ABSSSI) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's ABSSSI infection is caused by any of the following susceptible microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates)*, Staphylococcus haemolyticus*, *Staphylococcus lugdunensis, Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus, Streptococcus intermedius,* and *Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* or *Pseudomonas aeruginosa*

   If yes, continue to #3.
   If no, continue to #6.

3. Is Baxdela being used for an animal or human bite, necrotizing fasciitis, diabetic foot infection, decubitus ulcer formation, myonecrosis or ecthyma gangrenosum?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

4. Has an antimicrobial susceptibility test been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to ONE standard of care agent for acute bacterial skin or skin structure infections (ABSSSI) (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, vancomycin)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Baxdela

   If yes, **approve the 450mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #28 per 14 days for 1 fill.**

   If no, continue to #5.

5. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to ONE clinical standard of care agent: a gram positive targeting antibiotic (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin), a penicillin antibiotic (e.g., amoxicillin), a fluoroquinolone antibiotic (e.g., levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin antibiotic (e.g., ceftriaxone, cephalexin, cefazolin)

   If yes, **approve the 450mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #28 per 14 days for 1 fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) (ICD-10 J15.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's CABP infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates* only*), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila* or *Mycoplasma pneumoniae*

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

7. Is the request for continuation of care from an inpatient setting?

   If yes, **approve the 450mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #20 per 10 days for 1 fill.**

   If no, continue to #8.

8. Has an antimicrobial susceptibility test been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to at least TWO standard of care agents for community-acquired bacterial pneumonia (CABP) (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Baxdela

   If yes, **approve the 450mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #20 per 10 days for 1 fill.**

   If no, continue to #9.

9. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to at least TWO clinical standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

   If yes, **approve the 450mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #20 per 10 days for 1 fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DELAFLOXACIN (Baxdela)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. Baxdela is prescribed by or in consultation with an infectious disease (ID) specialist (a doctor who specializes in the treatment of infections)
   2. You have an acute bacterial skin or skin structure infection (ABSSSI: a type of skin condition)
   3. You have community-acquired bacterial pneumonia (CABP: a type of lung infection)

B. If you have an acute bacterial skin or skin structure infection, approval also requires:
   1. You are 18 years of age or older
   2. Your infection is caused by any of the following susceptible microorganisms (bacteria that the medication can work on): *Staphylococcus aureus* (including methicillin-resistant [MRSA] *and methicillin-susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, or Pseudomonas aeruginosa*
   3. You are NOT using Baxdela for an animal or human bite, necrotizing fasciitis (flesh eating disease), diabetic foot infection (infection caused by high blood sugar), decubitus ulcer formation (a type of skin injury), myonecrosis (dead muscle tissue) or ecthyma gangrenosum (a type of skin lesion)
   4. You meet ONE of the following:
      a. Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
         i. The bacteria at the infection site culture is resistant (medication will not work on that bacteria) to ONE standard of care medication for acute bacterial skin or skin structure infections (such as sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, vancomycin)
         ii. Baxdela will work against the bacteria
      b. If an antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a gram positive targeting antibiotic (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin), a penicillin (such as amoxicillin), a fluoroquinolone (such as levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin (such as ceftriaxone, cephalexin, cefazolin)

(Denial text continued on next page)

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DELAFLOXACIN

GUIDELINES FOR USE (CONTINUED)

C. If you have community-acquired bacterial pneumonia, approval also requires:

1. You are 18 years of age or older
2. Your infection is caused by any of the following susceptible microorganisms (bacteria that the medication can work on: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila or Mycoplasma pneumoniae
3. You meet ONE of the following:
   a. Your request is for continuation of care from an inpatient setting (a healthcare facility where medical treatment is given overnight or longer)
   b. Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
      i. The bacteria at the infection site culture is resistant (medication will not work on that bacteria) to at least TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
      ii. Baxdela will work against the bacteria
   c. If an antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) at least TWO clinical standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Baxdela.

REFERENCES

Baxdela [Prescribing Information]. Lincolnshire, Illinois: Melinta Therapeutics, Inc.; June 2021.

Created: 10/17
Effective: 07/22/26 Client Approval: 07/26 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DELGOCITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DELGOCITINIB	ANZUPGO	50242		GPI-10 (9027202000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe chronic hand eczema (CHE) (ICD-10 L30.8, L30.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a modified Investigator's Global Assessment for Chronic Hand Eczema (IGA-CHE) score of 3 or 4
   - The patient had a trial of, or a contraindication to, either the clinical standard of care agent: a topical corticosteroid of medium potency or greater (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR the preferred agent: a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Eucrisa (crisaborole), Opzelura (ruxolitinib), Zoryve (roflumilast) 0.15% cream, Vtama (tapinarof)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Will Anzupgo be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   - Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)], JAK inhibitors [e.g., Opzelura (ruxolitinib)], AhR agonists [e.g., Vtama (tapinarof)])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 4 months by HICL or GPI-10.**

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DELGOCITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DELGOCITINIB (Anzupgo)** requires the following rule(s) be met for approval:

A. You have moderate to severe chronic hand eczema (CHE: a type of skin condition)
B. You are 18 years of age or older
C. You have a modified Investigator's Global Assessment for Chronic Hand Eczema (IGA-CHE: a tool for evaluating the severity of your condition) score of 3 or 4
D. You have tried, or have a contraindication to (harmful for you to use), either the clinical standard of care medication: a topical corticosteroid of medium potency or greater (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment) OR the preferred medication: a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Eucrisa (crisaborole), Opzelura (ruxolitinib), Zoryve (roflumilast) 0.15% cream, Vtama (tapinarof)
F. You will NOT use Anzupgo concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
    1. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
    2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
    3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
    4. Potent immunosuppressants (such as azathioprine, cyclosporine)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DELGOCITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe chronic hand eczema (CHE) (ICD-10 L30.8, L30.9) **AND** meet the following criterion?
   - The patient has had improvement of symptoms

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Will Anzupgo be used concurrently with **ANY** of the following for the treatment of atopic dermatitis?
   - Other non-steroidal topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)], JAK inhibitors [e.g., Opzelura (ruxolitinib)], AhR agonists [e.g., Vtama (tapinarof)])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DELGOCITINIB (Anzupgo)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe chronic hand eczema (CHE: a type of skin condition)
   B. You have had improvement of symptoms
   C. You will NOT use Anzupgo concurrently (at the same time) with ANY of the following for the treatment of atopic dermatitis (a type of skin condition):
      1. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)], JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)], AhR [aryl hydrocarbon receptor] agonists [such as Vtama (tapinarof)])
      2. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      3. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      4. Potent immunosuppressants (such as azathioprine, cyclosporine)

   (Renewal denial text continued on next page)

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DELGOCITINIB

RENEWAL CRITERIA (CONTINUED)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Anzupgo.

REFERENCES

Anzupgo [Prescribing Information]. Madison, NJ: LEO Pharma A/S; July 2025.

Created: 08/25
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENILEUKIN DIFTITOX-CXDL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DENILEUKIN DIFTITOX-CXDL	LYMPHIR	49797		GPI-10 (2170002401)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Stage I-III cutaneous T-cell lymphoma (CTCL) (ICD-10 Group C84.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has relapsed or refractory disease
   - The patient has received at least one prior systemic therapy (e.g., methotrexate/pralatrexate, retinoids [e.g., acitretin, isotretinoin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DENILEUKIN DIFTITOX-CXDL (Lymphir)** requires the following rule(s) be met for approval:
   A. You have Stage I-III cutaneous T-cell lymphoma (CTCL: a type of blood cancer that affects the skin)
   B. You are 18 years of age or older
   C. You have relapsed or refractory disease (disease that has returned or did not respond to treatment)
   D. You have received at least one prior systemic therapy (treatment that targets the entire body such as methotrexate/pralatrexate, retinoids [such as acitretin, isotretinoin])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lymphir.

REFERENCES

Lymphir [Prescribing Information]. Cranford, NJ: Citius Pharmaceuticals, Inc.; August 2024.

Created: 11/25
Effective: 12/22/25 Client Approval: 12/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-BMWO-OSENVELT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DENOSUMAB-BMWO	OSENVELT		57292	GPI-14 (30044530222030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) OR bone metastases from a solid tumor **AND** meet the following criterion?
   - Osenvelt will be used to prevent skeletal-related events (e.g., bone fractures, bone pain requiring radiation)

   If yes, **approve for 12 months by GPID or GPI-14 for #1.7mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell tumor of bone (ICD-10 D48.0) **AND** meet the following criterion?
   - The patient's tumor is unresectable or surgical resection is likely to result in severe morbidity

   If yes, **approve for a total of 12 months as follows:**
   INITIAL REQUEST: Enter both authorizations.
   - **Approve for 1 month by GPID or GPI-14 for #5.1mL per 28 days.**
   - **Approve for 11 months by GPID or GPI-14 for #1.7mL per 28 days (Please enter a start date after the end date of the first authorization).**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months by GPID or GPI-14 for #1.7mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of hypercalcemia of malignancy **AND** meet the following criterion?
   - The patient is refractory to a bisphosphonate therapy (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

   If yes, **approve for a total of 12 months as follows:**
   INITIAL REQUEST: Enter both authorizations.
   - **Approve for 1 month by GPID or GPI-14 for #5.1mL per 28 days.**
   - **Approve for 11 months by GPID or GPI-14 for #1.7mL per 28 days (Please enter a start date after the end date of the first authorization).**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months by GPID or GPI-14 for #1.7mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-BMWO-OSENVELT

GUIDELINES FOR USE

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DENOSUMAB-BMWO-OSENVELT** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Multiple myeloma (a type of blood cancer)
   2. Bone metastases from a solid tumor (tumor has spread to the bone)
   3. Giant cell tumor of bone (noncancerous tumor)
   4. Hypercalcemia (high level of calcium in the blood) of malignancy (cancer)

B. If you have multiple myeloma or bone metastases from a solid tumor, approval also requires:
   1. Osenvelt will be used to prevent skeletal-related events (such as bone fractures, bone pain requiring radiation [a type of treatment])

C. If you have giant cell tumor of bone, approval also requires:
   1. Your tumor is unresectable (unable to remove by surgery) or surgical resection (removal) is likely to result in severe morbidity (illness)

D. If you have hypercalcemia of malignancy, approval also requires:
   1. You are refractory (disease did not respond to treatment) to a prior bisphosphonate therapy (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Osenvelt and Xgeva.

REFERENCES

Osenvelt [Prescribing Information]. Jersey City, NJ: Celltrion USA, Inc.; February 2025.
Xgeva [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; May 2025.

Created: 08/25
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-BMWO-STOBOCLO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DENOSUMAB-BMWO	STOBOCLO		57209	GPI-14 (3004453022E520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis (ICD-10 M81.0, Group M80.0)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient at high risk for fractures as defined as **ONE** of the following?
   - History of osteoporotic (fragility, low trauma) fracture(s)
   - Two or more risk factors for a fracture (e.g., history of multiple recent low trauma fractures, bone mineral density [BMD] T-score less than or equal to -2.5, corticosteroid use, use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin])
   - No prior treatment for osteoporosis, AND a FRAX score of at least 20% for any major fracture OR at least 3% for hip fracture

   If yes, **approve for 12 months by GPID or GPI-14 for #2 fills with a quantity limit of #1mL per fill.**

   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
   - The patient is unable to use oral therapy (upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)

   If yes, **approve for 12 months by GPID or GPI-14 for #2 fills with a quantity limit of #1mL per fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DENOSUMAB-BMWO-STOBOCLO

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have **ONE** of the following diagnoses?
   - Osteoporosis in a male patient (ICD-10 M81.0, Group M80.0)
   - Glucocorticoid-induced osteoporosis (ICD-10 M81.8, Group M80.8)

   If yes, continue to #5.
   If no, continue to #7.

5. Is the patient at high risk for fractures as defined as **ONE** of the following?
   - History of osteoporotic (fragility, low trauma) fracture(s)
   - Two or more risk factors for a fracture (e.g., history of multiple recent low trauma fractures, bone mineral density [BMD] T-score less than or equal to -2.5, corticosteroid use, use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin])

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Has the patient had a trial of or contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])?

   If yes, **approve for 12 months by GPID or GPI-14 for #2 fills with a quantity limit of #1mL per fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have **ONE** of the following diagnoses?
   - Bone loss in men receiving androgen deprivation therapy (e.g., Eligard [leuprolide], Zoladex [goserelin]) for non-metastatic prostate cancer
   - Bone loss in women receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, letrozole) for breast cancer

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DENOSUMAB-BMWO-STOBOCLO

GUIDELINES FOR USE (CONTINUED)

8. Does the patient meet **ALL** of the following criteria?
   - The patient is at high risk for fracture (e.g., history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin])
   - The patient had a trial of or contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])

   If yes, **approve for 12 months by GPID or GPI-14 for #2 fills with a quantity limit of #1mL per fill.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DENOSUMAB-BMWO-STOBOCLO** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Postmenopausal osteoporosis (a type of bone condition)
      2. Osteoporosis (a type of bone condition) in a male patient
      3. Glucocorticoid (steroid)-induced osteoporosis (a type of bone condition)
      4. Bone loss in men receiving androgen deprivation therapy (type of medication to lower hormone levels, such as Eligard [leuprolide], Zoladex [goserelin]) for non-metastatic prostate cancer (prostate cancer that has not spread to other parts of the body)
      5. Bone loss in women receiving adjuvant (add-on) aromatase inhibitor therapy (type of breast cancer medication, such as anastrozole, letrozole) for breast cancer

   (Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

B. If you have postmenopausal osteoporosis, approval also requires ONE of the following:
1. You are at high risk for fractures (a type of complete or partial break in a bone) as defined as ONE of the following:
   a. You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
   b. You have two or more risk factors for a fracture (a type of complete or partial break in a bone) (such as history of multiple recent low trauma [injury] fractures, bone mineral density [BMD] T-score [a type of lab test] of less than or equal to -2.5, corticosteroid [such as prednisone] use, use of gonadotropin-releasing hormone [GnRH] analogs [such as Synarel (nafarelin)])
   c. You have had no prior treatment for osteoporosis (a type of bone condition), AND you have a Fracture Risk Assessment Tool (FRAX: a type of test) score of at least 20 percent for any major fracture (a type of complete or partial break in a bone) OR at least 3 percent for a hip fracture
2. You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
3. You are unable to use oral therapy due to reasons such as upper gastrointestinal (GI: stomach and intestine) problems (such as unable to tolerate oral medications), lower GI problems (such as unable to absorb oral medications), trouble remembering to take oral medications or coordinating an oral bisphosphonate (such as Fosamax [alendronate]) with other oral medications or your daily routine

C. If you are a male with osteoporosis or you have glucocorticoid-induced osteoporosis, approval also requires:
1. You are at high risk for fractures (a type of complete or partial break in a bone) as defined as ONE of the following:
   a. You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
   b. You have two or more risk factors for a fracture (a type of complete or partial break in a bone) (such as history of multiple recent low trauma [injury] fractures, bone mineral density [BMD] T-score [a type of lab test] of less than or equal to -2.5, corticosteroid [such as prednisone] use, use of gonadotropin-releasing hormone [GnRH] analogs [such as Synarel (nafarelin)])
2. You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

D. If you are a man with bone loss who is receiving androgen deprivation therapy for non-metastatic prostate cancer or a woman with bone loss who is receiving adjuvant aromatase inhibitor therapy for breast cancer, approval also requires:

1. You are at high risk for fractures (a type of complete or partial break in a bone) (such as history of osteoporotic fracture, history of multiple recent low trauma [injury] fractures, corticosteroid [such as prednisone] use, or use of gonadotropin-releasing hormone [GnRH] analogs [such as Synarel (nafarelin)])
2. You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stoboclo and Prolia.

REFERENCES

Stoboclo [Prescribing Information]. Jersey City, New Jersey: Celltrion USA, Inc.; February 2025.
Prolia [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; May 2025.

Created: 08/25
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-PROLIA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DENOSUMAB	PROLIA		28656	GPI-14 (3004453000E520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis (ICD-10 M81.0, Group M80.0) **AND** meet the following criterion?
   - The patient had a trial of or contraindication to the preferred agent: Stoboclo (denosumab-bmwo)

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient at high risk for fractures as defined as **ONE** of the following?
   - History of osteoporotic (fragility, low trauma) fracture(s)
   - Two or more risk factors for a fracture (e.g., history of multiple recent low trauma fractures, bone mineral density [BMD] T-score less than or equal to -2.5, corticosteroid use, use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin])
   - No prior treatment for osteoporosis, AND a FRAX score of at least 20% for any major fracture OR at least 3% for hip fracture

   If yes, **approve for 12 months by GPID or GPI-14 for #2 fills with a quantity limit of #1mL per fill.**

   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
   - The patient is unable to use oral therapy (upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)

   If yes, **approve for 12 months by GPID or GPI-14 for #2 fills with a quantity limit of #1mL per fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DENOSUMAB-PROLIA

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have **ONE** of the following diagnoses?
   - Osteoporosis in a male patient (ICD-10 M81.0, Group M80.0)
   - Glucocorticoid-induced osteoporosis (ICD-10 M81.8, Group M80.8)

   If yes, continue to #5.
   If no, continue to #7.

5. Is the patient at high risk for fractures as defined as **ONE** of the following?
   - History of osteoporotic (fragility, low trauma) fracture(s)
   - Two or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone mineral density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as Synarel [nafarelin])

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
   - The patient had a trial of or contraindication to the preferred agent: Stoboclo (denosumab-bmwo)

   If yes, **approve for 12 months by GPID or GPI-14 for #2 fills with a quantity limit of #1mL per fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have **ONE** of the following diagnoses?
   - Bone loss in men receiving androgen deprivation therapy (e.g., Eligard [leuprolide], Zoladex [goserelin]) for non-metastatic prostate cancer
   - Bone loss in women receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, letrozole) for breast cancer

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DENOSUMAB-PROLIA

GUIDELINES FOR USE (CONTINUED)

8. Does the patient meet **ALL** of the following criteria?
   - The patient is at high risk for fracture (e.g., history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, use of GnRH analogs such as Synarel [nafarelin])
   - The patient had a trial of or contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
   - The patient had a trial of or contraindication to the preferred agent: Stoboclo (denosumab-bmwo)

   If yes, **approve for 12 months by GPID or GPI-14 for #2 fills with a quantity limit of #1mL per fill.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DENOSUMAB-PROLIA** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Postmenopausal osteoporosis (a type of bone condition)
      2. Osteoporosis (a type of bone condition) in a male patient
      3. Glucocorticoid (steroid)-induced osteoporosis (a type of bone condition)
      4. Bone loss in men receiving androgen deprivation therapy (type of medication to lower hormone levels, such as Eligard [leuprolide], Zoladex [goserelin]) for non-metastatic prostate cancer (prostate cancer that has not spread to other parts of the body)
      5. Bone loss in women receiving adjuvant (add-on) aromatase inhibitor therapy (type of breast cancer medication, such as anastrozole, letrozole) for breast cancer

   (Denial text continued on next page)

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DENOSUMAB-PROLIA

GUIDELINES FOR USE (CONTINUED)

B. If you have postmenopausal osteoporosis, approval also requires:

1. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Stoboclo (denosumab-bmwo)
2. You meet ONE of the following:
   a. You are at high risk for fractures (a type of complete or partial break in a bone) as defined as ONE of the following:
      i. You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
      ii. You have two or more risk factors for a fracture (a type of complete or partial break in a bone) (such as history of multiple recent low trauma [injury] fractures, bone mineral density [BMD] T-score [a type of lab test] of less than or equal to -2.5, corticosteroid [such as prednisone] use, use of gonadotropin-releasing hormone analogs [GnRH] [such as Synarel [nafarelin])
      iii. You have had no prior treatment for osteoporosis (a type of bone condition), AND you have a Fracture Risk Assessment Tool (FRAX: a type of test) score of at least 20 percent for any major fracture (a type of complete or partial break in a bone) OR at least 3 percent for a hip fracture
   b. You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
   c. You are unable to use oral therapy due to reasons such as upper gastrointestinal (GI: stomach and intestine) problems (such as unable to tolerate oral medications), lower GI problems (such as unable to absorb oral medications), trouble remembering to take oral medications or coordinating an oral bisphosphonate (such as Fosamax [alendronate]) with other oral medications or your daily routine

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GUIDELINES FOR USE (CONTINUED)

C. If you are a male with osteoporosis OR you have glucocorticoid-induced osteoporosis, approval also requires:
1. You are at high risk for fractures (a type of complete or partial break in a bone) as defined as ONE of the following:
   a. You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
   b. You have two or more risk factors for a fracture (a type of complete or partial break in a bone) (such as history of multiple recent low trauma [injury] fractures, bone mineral density [BMD] T-score [a type of lab test] of less than or equal to -2.5, corticosteroid [such as prednisone] use, use of gonadotropin-releasing hormone [GnRH] analogs [such as Synarel (nafarelin)])
2. You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Stoboclo (denosumab-bmwo)

D. If you are a man with bone loss who is receiving androgen deprivation therapy for non-metastatic prostate cancer or a woman with bone loss who is receiving adjuvant aromatase inhibitor therapy for breast cancer, approval also requires:
1. You are at high risk for fracture (a type of complete or partial break in a bone) (such as history of osteoporotic fracture, history of multiple recent low trauma [injury] fractures, corticosteroid [such as prednisone] use, use of gonadotropin-releasing hormone [GnRH] analogs (such as Synarel [nafarelin])
2. You have tried or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate], Reclast [zoledronic acid])
3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Stoboclo (denosumab-bmwo)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Prolia.

REFERENCES

Prolia [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; May 2025.

Created: 07/10
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 04/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DENOSUMAB-XGEVA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DENOSUMAB	XGEVA		29261	GPI-14 (30044530002030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) OR bone metastases from a solid tumor and meet **ALL** of the following criteria?
   - Xgeva will be used to prevent skeletal-related events (e.g., bone fractures, bone pain requiring radiation)
   - The patient had a trial of or contraindication to the preferred agent: Osenvelt (denosumab-bmwo)

   If yes, **approve for 12 months by GPID or GPI-14 for #1.7mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell tumor of bone (ICD-10 D48.0) and meet **ALL** of the following criteria?
   - The patient's tumor is unresectable or surgical resection is likely to result in severe morbidity
   - The patient had a trial of or contraindication to the preferred agent: Osenvelt (denosumab-bmwo)

   If yes, **approve for a total of 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #5.1mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #1.7mL per 28 days.**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #1.7mL per 28 days.**

   If no, continue to #3.

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DENOSUMAB-XGEVA

GUIDELINES FOR USE

3. Does the patient have a diagnosis of hypercalcemia of malignancy and meet **ALL** of the following criteria?
   - The patient is refractory to a bisphosphonate therapy (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])
   - The patient had a trial of or contraindication to the preferred agent: Osenvelt (denosumab-bmwo)

   If yes, **approve for a total of 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #5.1mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #1.7mL per 28 days.**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #1.7mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DENOSUMAB-XGEVA** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Multiple myeloma (a type of blood cancer)
      2. Bone metastases from a solid tumor (tumor has spread to the bone)
      3. Giant cell tumor of bone (noncancerous tumor)
      4. Hypercalcemia (high level of calcium in the blood) of malignancy (cancer)

   B. If you have multiple myeloma or bone metastases from a solid tumor, approval also requires:
      1. Xgeva will be used to prevent skeletal-related events (such as bone fractures, bone pain requiring radiation [a type of treatment])
      2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Osenvelt (denosumab-bmwo)

   C. If you have giant cell tumor of bone, approval also requires:
      1. Your tumor is unresectable (unable to remove by surgery) or surgical resection (removal) is likely to result in severe morbidity (illness)
      2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Osenvelt (denosumab-bmwo)

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DENOSUMAB-XGEVA

GUIDELINES FOR USE

D. If you have hypercalcemia of malignancy, approval also requires:

1. You are refractory (disease did not respond to treatment) to a prior bisphosphonate therapy (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Osenvelt (denosumab-bmwo)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xgeva.

REFERENCES

Xgeva [Prescribing Information]. Thousand Oaks, CA: Amgen; May 2025.

Created: 11/07
Effective: 01/01/26 Client Approval: 11/25/25 P&T Approval: 01/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEPEMOKIMAB-ULAA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEPEMOKIMAB-ULAA	EXDENSUR	51066		GPI-10 (4460403000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   - The patient has a blood eosinophil level of at least 150 cells/mcL within the past 12 months
   - Exdensur will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   - Exdensur will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma
   - The patient had a trial of or contraindication to THREE of the following preferred agents: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g., prednisone) burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring a hospitalization or emergency room visit within the past 12 months

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #3.

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DEPEMOKIMAB-ULAA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) (e.g., albuterol) reliever for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEPEMOKIMAB-ULAA (Exdensur)** requires the following rule(s) be met for approval:
   A. You have severe eosinophilic phenotype asthma (a type of inflammatory asthma)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or in consultation with a doctor specializing in allergy or pulmonary (relating to lungs/breathing) medicine
   D. You have a blood eosinophil (a type of white blood cell) level of at least 150 cells/mcL within the past 12 months
   E. Exdensur will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline
   F. You will NOT use Exdensur concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of inflammatory asthma)
   G. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko)

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DEPEMOKIMAB-ULAA

INITIAL CRITERIA (CONTINUED)

H. You meet ONE of the following:
   1. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   2. You have experienced at least ONE serious asthma exacerbation (worsening of symptoms) requiring a hospitalization or emergency room visit within the past 12 months
   3. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      a. Daytime asthma symptoms more than twice per week
      b. Any night waking due to asthma
      c. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      d. Any activity limitation due to asthma

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEPEMOKIMAB-ULAA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   - Exdensur will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma
   - The patient had a trial of or contraindication to THREE of the following preferred agents: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEPEMOKIMAB-ULAA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEPEMOKIMAB-ULAA (Exdensur)** requires the following rule(s) be met for renewal:

A. You have severe eosinophilic phenotype asthma (a type of inflammatory asthma)
B. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline
C. You will NOT use Exdensur concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of inflammatory asthma)
D. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko)
E. You have shown a clinical response as evidenced by ONE of the following:
    1. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Exdensur)
    2. You have decreased your use of rescue medications (such as albuterol)
    3. You have an increase in the percent predicted FEV1 (a type of lung test) from pretreatment baseline (before starting Exdensur)
    4. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exdensur.

REFERENCES

Exdensur [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline LLC; November 2025.

Created: 12/25
Effective: 01/12/26 Client Approval: 12/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DESIRUDIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DESIRUDIN	IPRIVASK	19072		GPI-10 (8333403000)	

GUIDELINES FOR USE

1. Is the request for Iprivask for the prevention (prophylaxis) of deep vein thrombosis (DVT) for a patient undergoing elective hip replacement surgery?

   If yes, **approve for a total of 35 days of treatment. Enter two authorizations as follows:**
   - **Approve for 12 days by HICL or GPI-10 for #24 vials.**
   - **Also enter one fill for 23 days by HICL or GPI-10 for #46 vials with a start date of 7 days following the initial approval.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DESIRUDIN (Iprivask)** requires that you are receiving Iprivask for the prevention of deep vein thrombosis (DVT; blood clot in a deep vein, usually in the legs) and you are undergoing elective hip replacement surgery.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iprivask.

REFERENCES

Iprivask [Prescribing Information]. Northbrook, IL: Marathon Pharmaceuticals; November 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/10
Client Approval: 04/20
P&T Approval: 11/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEUCRAVACITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEUCRAVACITINIB	SOTYKTU	48292		GPI-10 (9025052400)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Sotyktu will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Sotyktu
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEUCRAVACITINIB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of psoriatic arthritis (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Sotyktu will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEUCRAVACITINIB (Sotyktu)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)

   B. If you have moderate to severe plaque psoriasis, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
      3. You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
      4. You meet ONE of the following:
         a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
         b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) AND PUVA (phototherapy) for the treatment of plaque psoriasis
         c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
      5. You meet ONE of the following:
         a. You were previously stable on another biologic and are switching to Sotyktu
         b. You have psoriasis covering 3 percent or more of body surface area (BSA)
         c. You have psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp

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DEUCRAVACITINIB

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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DEUCRAVACITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   - Sotyktu will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Sotyktu will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEUCRAVACITINIB (Sotyktu)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)

   B. If you have moderate to severe plaque psoriasis, renewal also requires:
      1. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis) of at least 50 percent or more while on therapy
      2. You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

   (Renewal denial text continued on next page)

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DEUCRAVACITINIB

RENEWAL CRITERIA

C. If you have psoriatic arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Sotyktu concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sotyktu.

REFERENCES

Sotyktu [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2026.

Created: 09/22
Effective: 03/25/26 Client Approval: 03/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEURUXOLITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEURUXOLITINIB PHOSPHATE	LEQSELVI	49773		GPI-10 (9073102060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe alopecia areata (ICD-10 Group L63) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has had at least 50% scalp hair loss, as measured by the Severity of Alopecia Tool (SALT), for more than 6 months
   - Leqselvi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Litfulo (ritlecitinib)], PDE-4 inhibitor) for the treatment of alopecia areata
   - The patient had a trial of or contraindication to BOTH of the following preferred agents: Litfulo (ritlecitinib), Olumiant (baricitinib)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **TWO** of the following clinical standard of care agents (from different categories)?
   - Intralesional corticosteroid (e.g., triamcinolone acetonide)
   - Topical corticosteroid (e.g., fluocinolone acetonide, betamethasone dipropionate, clobetasol propionate)
   - Minoxidil (e.g., minoxidil 5% solution)
   - Short contact anthralin
   - Topical immunotherapy (e.g., squaric acid dibutyl ester, diphencyprone/diphenylcyclopropenone)
   - Systemic treatments (e.g., psoralen plus UV-A [PUVA], prednisone, cyclosporine, methotrexate)

     If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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DEURUXOLITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEURUXOLITINIB (Leqselvi)** requires the following rule(s) be met for approval:

A. You have severe alopecia areata (a type of hair loss)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You have had at least 50 percent scalp hair loss, as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool), for more than 6 months
E. You will NOT use Leqselvi concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Litfulo (ritlecitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata (a type of hair loss)
F. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Litfulo (ritlecitinib), Olumiant (baricitinib)
G. You have tried or have a contraindication to TWO of the following clinical standard of care medications (from different categories):
    1. Intralesional corticosteroid (such as triamcinolone acetonide)
    2. Topical corticosteroid (such as fluocinolone acetonide, betamethasone dipropionate, clobetasol propionate)
    3. Minoxidil (such as minoxidil 5% solution)
    4. Short contact anthralin
    5. Topical immunotherapy (such as squaric acid dibutyl ester, diphencyprone/diphenylcyclopropenone)
    6. Systemic treatments (such as psoralen plus UV-A [PUVA: a type of light therapy], prednisone, cyclosporine, methotrexate)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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DEURUXOLITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe alopecia areata (ICD-10 Group L63) and meet **ALL** of the following criteria?
   - The patient has had improvement while on therapy (e.g., scalp hair coverage)
   - Leqselvi will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Litfulo (ritlecitinib)], PDE-4 inhibitor) for the treatment of alopecia areata
   - The patient had a trial of or contraindication to BOTH of the following preferred agents: Litfulo (ritlecitinib), Olumiant (baricitinib)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
     If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **DEURUXOLITINIB (Leqselvi)** requires the following rule(s) be met for renewal:
     A. You have severe alopecia areata (a type of hair loss)
     B. You have experienced improvement while on therapy (such as scalp hair coverage)
     C. You will NOT use Leqselvi concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Litfulo (ritlecitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata (a type of hair loss)
     D. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Litfulo (ritlecitinib), Olumiant (baricitinib)

     NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leqselvi.

REFERENCES

Leqselvi [Prescribing Information]. Whippany, NJ: Sun Pharmaceutical Industries, Inc.; July 2024.

Created: 06/25
Effective: 06/10/26 Client Approval: 06/26 P&T Approval: 04/24

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DEUTETRABENAZINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEUTETRABENAZINE	AUSTEDO, AUSTEDO XR	44192		GPI-10 (6238003000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease (ICD-10 G10) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or movement disorder specialist
   - The patient had a trial of or contraindication to the preferred agent: Ingrezza (valbenazine)

   If yes, **approve for 12 months as follows:**
   INITIAL REQUESTS for XR formulation:
   FIRST APPROVAL: Please override the quantity limit coded on the formulary by selecting the "QL Only" override: Approve for 6 weeks by GPID or GPI-14 for all of the following:
   - **6-12-24mg XR titration kit: #42 per 28 days for 1 fill.**
   - **12-18-24-30mg XR titration kit: #28 per 28 days for 1 fill.**
   - **6mg XR: #6 per day.**
   - **12mg XR: #4 per day.**
   - **18mg XR: #2 per day.**
   - **24mg XR: #2 per day.**

   SECOND APPROVAL: Approve for 46 weeks by HICL or GPI-10.

   SUBSEQUENT REQUESTS for XR formulation: Approve for 12 months by HICL or GPI-10.

   For IR formulation: Approve for 12 months by HICL or GPI-10.

   If no, continue to #2.

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DEUTETRABENAZINE

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe tardive dyskinesia (TD) (ICD-10 G24.01) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's TD has been present for at least 3 months
   - Therapy is prescribed by or in consultation with a neurologist, movement disorder specialist, or psychiatrist
   - The patient has a prior history of using antipsychotic medications (e.g., aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if the patient is 60 years of age or older) as documented in the prescription claims history
   - The patient had a trial of or contraindication to the preferred agent: Ingrezza (valbenazine)

   If yes, **approve for 12 months as follows:**
   INITIAL REQUESTS for XR formulation:
   FIRST APPROVAL: Please override the quantity limit coded on the formulary by selecting the "QL Only" override: Approve for 6 weeks by GPID or GPI-14 for all of the following:
   - **6-12-24mg XR titration kit: #42 per 28 days for 1 fill.**
   - **12-18-24-30mg XR titration kit: #28 per 28 days for 1 fill.**
   - **6mg XR: #6 per day.**
   - **12mg XR: #4 per day.**
   - **18mg XR: #2 per day.**
   - **24mg XR: #2 per day.**

   SECOND APPROVAL: Approve for 46 weeks by HICL or GPI-10.

   SUBSEQUENT REQUESTS for XR formulation: Approve for 12 months by HICL or GPI-10.

   For IR formulation: Approve for 12 months by HICL or GPI-10.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DEUTETRABENAZINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DEUTETRABENAZINE (Austedo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)
   2. Moderate to severe tardive dyskinesia (TD: uncontrolled body movements)

B. If you have chorea associated with Huntington's disease, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or movement disorder specialist
   3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ingrezza (valbenazine)

C. If you have moderate to severe tardive dyskinesia, approval also requires:
   1. You are 18 years of age or older
   2. Your moderate to severe tardive dyskinesia (uncontrolled body movements) has been present for at least 3 months
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), movement disorder specialist, or psychiatrist (a type of mental health doctor)
   4. You have a prior history of using antipsychotic medications (such as aripiprazole, haloperidol, ziprasidone) or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history
   5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ingrezza (valbenazine)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Austedo and Austedo XR.

REFERENCES

Austedo, Austedo XR [Prescribing Information]. Parsippany, NJ: Teva Neuroscience, Inc.; February 2025.

Created: 04/17
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEXMEDETOMIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEXMEDETOMIDINE HCL	IGALMI	20971		GPI-10 (6020603010)	ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of acute agitation associated with schizophrenia or bipolar I or II disorder (ICD-10 Groups F20, F31) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist
   - The patient had a trial of or contraindication to THREE antipsychotics (e.g., olanzapine, ziprasidone, haloperidol)

   If yes, **approve the requested strength for 1 month by GPID or GPI-14 with a quantity limit of #3 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEXMEDETOMIDINE (Igalmi)** requires the following rule(s) be met for approval:
   A. You have acute (short-term) agitation associated with schizophrenia (a type of mental health disorder) or bipolar I or II disorder (a type of mood disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor)
   D. You have tried or have a contraindication to (harmful for you to use) THREE antipsychotics (such as olanzapine, ziprasidone, haloperidol)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEXMEDETOMIDINE

RENEWAL CRITERIA

1. Is the request for the treatment of acute agitation associated with schizophrenia or bipolar I or II disorder (ICD-10 Groups F20, F31)?

   If yes, continue to #2.
   If no, do no approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient's maintenance therapy for the underlying psychiatric disorder currently being adjusted/optimized to reduce or eliminate the need for continued PRN medications for acute agitation?

   If yes, **approve the requested strength for 3 months by GPID or GPI-14 with a quantity limit of #3 per day.**

   If no, continue to #3.

3. Have attempts to adjust medications been exhausted **AND** the physician has determined that chronic PRN medications are required for the continued safety of the patient or caregivers?

   If yes, **approve the requested strength for 6 months by GPID or GPI-14 with a quantity limit of #3 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEXMEDETOMIDINE (Igalmi)** requires the following rule(s) be met for renewal:
   A. You have acute (short-term) agitation associated with schizophrenia (a type of mental health disorder) or bipolar I or II disorder (a type of mood disorder)
   B. You meet ONE of the following:
      1. Your maintenance therapy for the underlying psychiatric (mental) disorder is currently being adjusted/optimized to reduce or eliminate the need for continued PRN (as needed) medications for the treatment of acute agitation
      2. Attempts to adjust medications have been exhausted AND your physician (doctor) has determined that chronic PRN (long-term as needed) medications are required for the continued safety of you or your caregivers

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DEXMEDETOMIDINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Igalmi.

REFERENCES

Igalmi [Prescribing Information]. New Haven, CT: BioXcel Therapeutics, Inc.; April 2022.

Created: 05/22
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DEXTROMETHORPHAN-QUINIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DEXTROMETHORPHAN HBR/QUINIDINE	NUEDEXTA	37278		GPI-10 (6260990230)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pseudobulbar affect (PBA) (ICD-10 F48.2)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DEXTROMETHORPHAN-QUINIDINE (Nuedexta)** requires the following rule(s) be met for approval:
   A. You have pseudobulbar affect (uncontrollable, inappropriate laughing and/or crying due to a nervous system disorder)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuedexta.

REFERENCES

Nuedexta [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceuticals, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/15

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIABETIC TEST STRIPS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BLOOD SUGAR DIAGNOSTIC, BLOOD SUGAR DIAGNOSTIC, DISC, BLOOD SUGAR DIAGNOSTIC, DRUM	DIABETIC TEST STRIPS VARIOUS		25200	GPI-14 (94100030006100)	

CSR NOTE: Requests for blood glucose (diabetic) test strips manufactured by Abbott (FreeStyle and Precision) will adjudicate at the point of service with no restrictions. Non-formulary test strips will require prior authorization.

GUIDELINES FOR USE

1. Has the patient tried one of the following preferred blood glucose (diabetic) meters and test strips by Abbott: FreeStyle or Precision?

   If yes, **approve open-ended by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient require the use of a non-preferred blood glucose test strip due to significant visual and/or cognitive impairment?

   If yes, **approve open-ended by GPID or GPI-14.**
   If no, continue to #3.

3. Is the prescriber requesting a non-preferred test strip due to a need for data management software? [**Note:** The preferred test strips include FreeStyle and Precision by Abbott]

   If yes, do not approve, and recommend the prescriber contact Abbott for data management software and a connection cable for the meter.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #4.

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DIABETIC TEST STRIPS

GUIDELINES FOR USE (CONTINUED)

4. Does the patient require the use of a non-preferred blood glucose test strip based on his/her use of another manufacturer's companion insulin pump?

   If yes, **approve open-ended by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIABETIC TEST STRIPS** requires ONE of following rules be met for approval:
   A. You have tried ONE preferred blood glucose (diabetic) meter and test strips. The preferred meters and test strips are FreeStyle and Precision by Abbott
   B. You require a non-preferred blood glucose test strip due to significant visual and/or cognitive impairment (problems with sight and/or memory and thinking)
   C. You require a non-preferred blood glucose test strip because you use another manufacturer's companion insulin pump

   Request for non-preferred test strips will not be approved if due to a need for data management software. Please note that data management software is available for the formulary test strip products. Please contact Abbott for data management software and a connection cable for the meter.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different product or get us more information if it will allow us to approve this request.

RATIONALE

The intent of this prior authorization is to encourage the use of cost-effective formulary preferred glucose testing strips before considering coverage of non-preferred alternatives.

REFERENCES

Drug Facts and Comparisons (online version), Blood Glucose Meters. Available at http://online.factsandcomparisons.com.
American Diabetes Association. Standards of Medical Care in Diabetes- 2017. Diabetes Care 2017; 40 (suppl 1): S11-S135.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/08/21
Created: 01/12
Client Approval: 01/21
P&T Approval: 08/14

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIAZEPAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIAZEPAM	VALTOCO	01615		GPI-10 (7210003000)	BRAND = VALTOCO

GUIDELINES FOR USE

1. Does the patient have a diagnosis of epilepsy (ICD-10 Group G40) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Valtoco will be used for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (seizure clusters, acute repetitive seizures) that are distinct from the patient's usual seizure pattern

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIAZEPAM (Valtoco)** requires the following rule(s) be met for approval:
   A. You have epilepsy (a type of brain disorder)
   B. You are 2 years of age or older
   C. Valtoco will be used for the acute (short-term) treatment of intermittent, stereotypic episodes of frequent seizure activity (a condition of increased seizure activity) (seizure clusters, acute repetitive seizures) that are different from your usual seizure pattern

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Valtoco.

REFERENCES

Valtoco [Prescribing Information]. San Diego, CA: Neurelis, Inc.; June 2025.

Created: 05/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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DIAZOXIDE CHOLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIAZOXIDE CHOLINE	VYKAT XR	50391		GPI-10 (3090283020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hyperphagia (ICD-10 R63.2) and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - The patient has a genetically confirmed Prader-Willi syndrome (PWS)
   - Therapy is prescribed by or in consultation with an endocrinologist, geneticist, or neurologist

   If yes, **approve all strengths for 6 months by GPID or GPI-14 as follows:**
   - **25mg: #4 per day.**
   - **75mg: #7 per day.**
   - **150mg: #3 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIAZOXIDE CHOLINE (Vykat XR)** requires the following rule(s) be met for approval:
   A. You have hyperphagia (extreme hunger)
   B. You are 4 years of age or older
   C. You have genetically confirmed Prader-Willi syndrome (PWS: a type of generic disorder)
   D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (doctor who treats gene disorders), or neurologist (a type of brain and nervous system doctor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIAZOXIDE CHOLINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hyperphagia (ICD-10 R63.2) and meet **ALL** of the following criteria?
   - The patient's hyperphagia is associated with Prader-Willi syndrome (PWS)
   - The patient has had clinical improvement

   If yes, **approve all strengths for 12 months by GPID or GPI-14 as follows:**
   - **25mg: #4 per day.**
   - **75mg: #7 per day.**
   - **150mg: #3 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIAZOXIDE CHOLINE (Vykat XR)** requires the following rule(s) be met for renewal:
   A. You have hyperphagia (extreme hunger)
   B. Your hyperphagia is associated with Prader-Willi syndrome (PWS: a type of generic disorder)
   C. You have had clinical improvement

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vykat XR.

REFERENCES

Vykat XR [Prescribing Information]. Redwood City, CA: Soleno Therapeutics, Inc.; March 2025.

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DICHLORPHENAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DICHLORPHENAMIDE	KEVEYIS, ORMALVI, DICHLORPHENAMIDE	03642		GPI-10 (3710002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary hyperkalemic periodic paralysis or related variants (ICD-10 G72.3), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has tried acetazolamide AND a thiazide diuretic (i.e., hydrochlorothiazide)
   - The patient does NOT have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use with high-dose aspirin

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary hypokalemic periodic paralysis or related variants (ICD-10 G72.3), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has tried acetazolamide AND a potassium-sparing diuretic (i.e., spironolactone, triamterene)
   - The patient does NOT have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use with high-dose aspirin

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DICHLORPHENAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DICHLORPHENAMIDE (Keveyis, Ormalvi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood) or related variants
   2. Primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood) or related variants

B. If you have primary hyperkalemic periodic paralysis or related variants, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   3. You have tried acetazolamide AND a thiazide diuretic (hydrochlorothiazide)
   4. You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin at the same time

C. If you have primary hypokalemic periodic paralysis or related variants, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   3. You have tried acetazolamide AND a potassium-sparing diuretic (spironolactone, triamterene)
   4. You do NOT have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow), or a health condition that requires you to use high-dose aspirin at the same time

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DICHLORPHENAMIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants (ICD-10 G72.3) **AND** meet the following criterion?
   - The patient has experienced at least TWO fewer attacks per week from baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DICHLORPHENAMIDE (Keveyis, Ormalvi)** requires the following rule(s) be met for renewal:
   A. You have primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood), primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood), or related variants
   B. You have experienced at least TWO fewer attacks per week from baseline (before you started treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Keveyis or Ormalvi.

REFERENCES

Keveyis [Prescribing Information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; August 2024.
Ormalvi [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd.; February 2024.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIFELIKEFALIN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIFELIKEFALIN ACETATE	KORSUVA	47561		GPI-10 (9969002010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderate to severe pruritus associated with chronic kidney disease and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is undergoing hemodialysis (HD)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIFELIKEFALIN (Korsuva)** requires the following rule(s) be met for approval:
   A. You have moderate to severe pruritus (itching) associated with chronic kidney disease
   B. You are 18 years of age or older
   C. You are undergoing hemodialysis (HD: a process of removing excess water and toxins from the blood)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Korsuva.

REFERENCES

Korsuva [Prescribing Information]. Stamford, CT: Cara Therapeutics, Inc.; December 2021.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/22
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIGOXIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIGOXIN	DIGOXIN, LANOXIN		00130	GPI-14 (31200010000303)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of heart failure (ICD-10 Group I50)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic atrial fibrillation (ICD-10 Group I48.2) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIGOXIN (Lanoxin)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Heart failure (a type of heart condition)
      2. Chronic atrial fibrillation (a type of heart condition)
   B. If you have chronic atrial fibrillation, approval also requires:
      1. You are 18 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lanoxin.

REFERENCES

Lanoxin [Prescribing Information]. Bannockburn, IL: Advanz Pharma Corp; December 2024.

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DIHYDROERGOTAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIHYDROERGOTAMINE MESYLATE	TRUDHESA	00155		GPI-10 (6700003011)	BRAND = TRUDHESA

GUIDELINES FOR USE

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Trudhesa will NOT be used concurrently with any other dihydroergotamine or ergotamine product (e.g., Migranal [dihydroergotamine], Ergomar [ergotamine])

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient had a trial of or contraindication to **ALL** of the following preferred agents?
   - Two triptans (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan], Relpax [eletriptan])
   - One generic dihydroergotamine product (e.g., dihydroergotamine mesylate 1mg/mL, dihydroergotamine mesylate 0.5mg/spry)
   - One CGRP inhibitor: Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for the acute treatment of cluster headache (ICD-10 Groups G44.00, G44.01, G44.02) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Trudhesa will NOT be used concurrently with any other dihydroergotamine or ergotamine product (e.g., Migranal [dihydroergotamine], Ergomar [ergotamine])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient had a trial of or contraindication to **BOTH** of the following preferred agents?
   - One triptan: Imitrex (sumatriptan injection, sumatriptan intranasal), Zomig (zolmitriptan intranasal)
   - One generic dihydroergotamine injectable (e.g., dihydroergotamine mesylate 1mg/mL) or generic dihydroergotamine intranasal (e.g., dihydroergotamine mesylate 0.5mg/spry)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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DIHYDROERGOTAMINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DIHYDROERGOTAMINE (Trudhesa)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Acute (quick onset) treatment of migraines (a type of headache)
   2. Acute (quick onset) treatment of cluster headache (a type of headache)

B. If the request is for the acute treatment of migraines, approval also requires:
   1. You are 18 years of age or older
   2. You will NOT use Trudhesa concurrently (at the same time) with any other dihydroergotamine or ergotamine medication (such as Migranal [dihydroergotamine], Ergomar [ergotamine])
   3. You have tried or have a contraindication to (harmful for you to use) ALL of the following preferred medications:
      a. Two triptans (such as Imitrex [sumatriptan], Maxalt [rizatriptan], Relpax [eletriptan])
      b. One generic dihydroergotamine product (such as dihydroergotamine mesylate 1mg/mL, dihydroergotamine mesylate 0.5mg/spry)
      c. One calcitonin gene-related peptide (CGRP) inhibitor: Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)

C. If the request is for the acute treatment of cluster headache, approval also requires:
   1. You are 18 years of age or older
   2. You will NOT use Trudhesa concurrently (at the same time) with any other dihydroergotamine or ergotamine medication (such as Migranal [dihydroergotamine], Ergomar [ergotamine])
   3. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications:
      a. One triptan: Imitrex (sumatriptan injection, sumatriptan intranasal), Zomig (zolmitriptan intranasal)
      b. One generic dihydroergotamine injectable (e.g., dihydroergotamine mesylate 1mg/mL) or generic dihydroergotamine intranasal (e.g., dihydroergotamine mesylate 0.5mg/spry)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trudhesa.

REFERENCES

Trudhesa [Prescribing Information]. Seattle, WA: Impel NeuroPharma Inc.; September 2021.

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DIMETHYL FUMARATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIMETHYL FUMARATE	TECFIDERA, DIMETHYL FUMARATE	40168		GPI-10 (6240552500)	FDB ROUTE ≠ MISCELL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for generic dimethyl fumarate?

   If yes, **approve generic dimethyl fumarate for 12 months by HICL or GPI-10 with a quantity limit of #2 per day and override 'Generic Only' field.**
   If no, continue to #3.

3. Is the request for brand Tecfidera **AND** the patient meets the following criterion?
   - The patient had a trial of generic dimethyl fumarate

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIMETHYL FUMARATE (Tecfidera)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease goes away and returns), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. If you are requesting brand Tecfidera, approval also requires:
      1. You have tried generic dimethyl fumarate

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DIMETHYL FUMARATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Tecfidera.

REFERENCES

Tecfidera [Prescribing Information]. Cambridge, MA: Biogen Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DINUTUXIMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DINUTUXIMAB	UNITUXIN	42038		GPI-10 (2135602800)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of high-risk neuroblastoma (HRNB) and meet **ALL** of the following criteria?
   - The patient is younger than 18 years of age
   - Unituxin will be used in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA)
   - The patient has achieved a partial response to prior first-line multi-agent, multimodal therapy (e.g., chemotherapy, surgery, radiation, stem cell transplant)
   - The patient has NOT undergone 5 cycles of Unituxin

   If yes, **approve for 12 months by HICL or GPI-10 with a total fill count of 5.**
   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DINUTUXIMAB (Unituxin)** requires the following rule(s) be met for approval:
   A. You have high-risk neuroblastoma (HRNB: a type of cancer)
   B. You are younger than 18 years of age
   C. Unituxin will be used together with a granulocyte-macrophage colony-stimulating factor (GM-CSF: a type of medication used to make more white blood cells), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA) (types of medications used to treat cancer)
   D. You have shown a partial response (the cancer partly responded to treatment, but still did not go away) to prior first-line multi-agent, multimodal therapy (therapy that includes many medications and ways to treat your condition, such as chemotherapy, surgery, radiation, stem cell transplant)
   E. You have NOT received 5 cycles of Unituxin

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Unituxin.

REFERENCES

Unituxin [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; October 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DIROXIMEL FUMARATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DIROXIMEL FUMARATE	VUMERITY	46164		GPI-10 (6240553000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DIROXIMEL FUMARATE (Vumerity)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease goes away and returns), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vumerity.

REFERENCES

Vumerity [Prescribing Information]. Cambridge, MA: Biogen Inc.; September 2024.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONANEMAB-AZBT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DONANEMAB-AZBT	KISUNLA	49736		GPI-10 (6205052201)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Alzheimer's disease (ICD-10 Group G30) and meet **ALL** of the following criteria?
   - The patient is 60 years of age or older
   - The patient has mild cognitive impairment or mild dementia
   - Therapy is prescribed by or in consultation with a neurologist or psychiatrist
   - The patient had an amyloid pathology confirmed by positron emission tomography (PET) or detected by CSF-based testing (e.g., Aβ42, total tau [T-tau], phosphorylated tau [P-tau])
   - The patient has a Clinical Dementia Rating (CDR) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE) score of 20-28 at baseline
   - The patient has Alzheimer’s Association Workgroup Clinical Stage 3 (cognitive impairment but mostly maintains independence on activities of daily living [ADL]) or Clinical Stage 4 (cognitive impairment with mild functional impairments on instrumental ADLs but independence in basic ADLs) Alzheimer’s disease
   - The patient had a baseline brain MRI within 1 year prior to treatment
   - The patient had genotype testing to determine apolipoprotein E ε4 (ApoE ε4) status prior to initiation of treatment OR the patient/caregiver has been counseled on the risk of treatment and has waived genotype testing
   - The patient is NOT at increased risk of cerebral bleeding (e.g., evidence of cerebral micro- or macrohemorrhages, superficial siderosis, vasogenic edema, aneurysms or vascular malformations, lacunar infarcts or severe small vessel or white matter disease on screening MRI, uncontrolled bleeding disorder, platelet count less than 50,000 or international normalized ratio greater than 1.5)
   - Kisunla will NOT be used concurrently with any other anti-amyloid agent (e.g., Leqembi [lecanemab-irmb], Leqembi IQLIK [lecanemab-irmb]), anticoagulant (e.g., warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (e.g. Plavix [clopidogrel] with aspirin) (monotherapy antiplatelet is acceptable)

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DONANEMAB-AZBT

INITIAL CRITERIA (CONTINUED)

If yes, **approve for a total of 7 months by HICL or GPI-10. Please enter four authorizations as follows:**

- **FIRST APPROVAL: Approve for 1 month with a quantity limit of #20mL per 28 days for 1 fill.**
- **SECOND APPROVAL: Approve for 1 month with a quantity limit of #40mL per 28 days for 1 fill (please enter a start date of 3 days BEFORE the END date of the first approval).**
- **THIRD APPROVAL: Approve for 1 month with a quantity limit of #60mL per 28 days for 1 fill (please enter a start date of 3 days BEFORE the END date of the second approval).**
- **FOURTH APPROVAL: Approve for 4 months with a quantity limit of #80mL per 28 days (please enter a start date of 3 days BEFORE the END date of the third approval).**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DONANEMAB-AZBT (Kisunla)** requires the following rule(s) be met for approval:

A. You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
B. You are 60 years of age or older
C. You have mild cognitive impairment (decreased ability to process, understand, store and remember information) or mild dementia (a type of memory disorder) due to Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
D. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or psychiatrist (a type of mental health doctor)
E. You had an amyloid pathology (abnormal buildup of a type of protein) confirmed by positron emission tomography (PET: a type of imaging test) or detected by cerebrospinal fluid (CSF: a type of liquid in the brain and spinal cord)-based testing (such as amyloid-beta 42 [Aβ42], total tau [T-tau], phosphorylated tau [P-tau]) (types of lab tests)
F. You have a Clinical Dementia Rating (CDR: a tool for evaluating memory loss) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE: a test used to evaluate memory, thinking, and understanding) score of 20 to 28 at baseline (before treatment)

(Initial denial text continued on next page)

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DONANEMAB-AZBT

INITIAL CRITERIA (CONTINUED)

G. You have Alzheimer's Association Workgroup Clinical Stage 3 (cognitive impairment [decreased ability to process, understand, store and remember information] but mostly maintains independence on activities of daily living [ADL: basic everyday tasks]) or Clinical Stage 4 (cognitive impairment with mild functional impairments on instrumental ADLs but independence in basic ADLs) Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
H. You have had a baseline brain MRI (magnetic resonance imaging: a type of imaging lab) within 1 year prior to treatment
I. You had genotype testing (a type of lab test) to determine apolipoprotein E ε4 (ApoE ε4: a type of gene) status prior to initiation of treatment OR you/your caregiver have been counseled on the risk of treatment and have waived genotype testing
J. You are NOT at an increased risk of cerebral bleeding (such as evidence of cerebral microhemorrhages [small amount of bleeding in the brain] or macrohemorrhages [large amount of bleeding in the brain], superficial siderosis [a type of small bleeds in the brain], vasogenic edema [a type of brain swelling], aneurysms [weak bulging spot in the blood vessel] or vascular malformations [abnormal blood vessels], lacunar infarcts [brain stroke] or severe small vessel [damaged small blood vessels in the brain] or white matter disease [damaged nerve fibers in the brain] on screening magnetic resonance imaging [MRI: a type of imaging lab], uncontrolled bleeding disorder, platelet [a type of blood cell] count less than 50,000 or international normalized ratio [a blood test to check how long it takes your blood to clot] greater than 1.5)
K. You will NOT use Kisunla concurrently (at the same time) with any other anti-amyloid medication (such as Leqembi [lecanemab-irmb], Leqembi IQLIK [lecanemab-irmb]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DONANEMAB-AZBT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Alzheimer's disease (ICD-10 Group G30)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is this a first renewal request? (**NOTE:** Renewal request after the Initial approval of 7 months.)

   If yes, continue to #3.
   If no, continue to #6.

3. Does the patient meet **ALL** of the following criteria?
   - The patient has NOT progressed to moderate or severe Alzheimer's disease (dementia with moderate to severe functional impairment) as assessed by Mini Mental Status Exam or Clinical Dementia Rating (CDR-SB) scale and functional status (ADL impairment)
   - Kisunla will NOT be used concurrently with any other anti-amyloid agent (e.g., Leqembi [lecanemab-irmb], Leqembi IQLIK [lecanemab-irmb]), anticoagulant (e.g., warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (e.g. Plavix [clopidogrel] with aspirin) (monotherapy antiplatelet is acceptable)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient shown evidence of amyloid-related imaging abnormalities (ARIA) on an MRI scan?

   If yes, continue to #5.
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #80mL per 28 days.**

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DONANEMAB-AZBT

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have amyloid-related imaging abnormalities with edema/effusion (ARIA-E) or amyloid-related imaging abnormalities with hemorrhage or superficial siderosis (ARIA-H) and meet **ALL** of the following criteria?
   - The patient does NOT have severe symptoms (e.g., multiple ARIA episodes, macrohemorrhages, 10 or more microhemorrhages since the start of treatment, 3 or more superficial siderosis since the start of treatment, severe ARIA, need for anticoagulation)
   - The patient has moderate ARIA (with or without symptoms) and the provider has suspended infusions until a repeat MRI shows ARIA-E has resolved or ARIA-H has stabilized, OR the patient has asymptomatic mild ARIA with continued MRI monitoring until ARIA-E has resolved or ARIA-H has stabilized

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #80mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Is this a subsequent renewal request? (**NOTE**: Renewal request after the first renewal approval of 12 months.)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

7. Does the patient meet **ALL** of the following criteria?
   - The patient has NOT progressed to moderate or severe Alzheimer's disease (dementia with moderate to severe functional impairment) as assessed by Mini Mental Status Exam or Clinical Dementia Rating (CDR-SB) scale and functional status (ADL impairment)
   - Kisunla will NOT be used concurrently with any other anti-amyloid agent (e.g., Leqembi [lecanemab-irmb], Leqembi IQLIK [lecanemab-irmb]), anticoagulant (e.g., warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (e.g. Plavix [clopidogrel] with aspirin) (monotherapy antiplatelet is acceptable)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #80mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DONANEMAB-AZBT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DONANEMAB-AZBT (Kisunla)** requires the following rule(s) be met for renewal:

A. You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)

B. If the request is for the first renewal request, renewal also requires:

1. You have NOT progressed to moderate or severe Alzheimer's disease (dementia [a type of memory disorder] with moderate to severe functional impairment) as assessed by Mini Mental Status Exam (a test used to evaluate memory, thinking, and understanding) or Clinical Dementia Rating (CDR-SB: a tool for evaluating memory loss) scale and functional status (activities of daily living [ADL: basic everyday tasks] impairment)
2. You will NOT use Kisunla concurrently (at the same time) with any other anti-amyloid medication (such as Leqembi [lecanemab-irmb], Leqembi IQLIK [lecanemab-irmb]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

(Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You do NOT have evidence of amyloid-related imaging abnormalities (ARIA: abnormal differences in the brain) on a magnetic resonance imaging (MRI: a type of imaging) scan
   b. You have a magnetic resonance imaging (MRI: a type of imaging) scan showing amyloid-related imaging abnormalities with edema/effusion (ARIA-E: a type of brain swelling) or amyloid-related imaging abnormalities with hemorrhage or superficial siderosis (ARIA-H: a type of small bleed in the brain) and meet ALL of the following:
      i. You do NOT have severe symptoms (such as multiple amyloid-related imaging abnormalities [ARIA: abnormal differences in the brain] episodes, macrohemorrhages [large amount of bleeding in the brain], 10 or more microhemorrhages [small amount of bleeding in the brain] since the start of treatment, 3 or more superficial siderosis [a type of small bleeds in the brain] since the start of treatment, severe ARIA, need for anticoagulation [a type of treatment to thin the blood])
      ii. You have moderate amyloid-related imaging abnormalities (ARIA: abnormal differences in the brain) (with or without symptoms) and your doctor has suspended (stopped) infusions until a repeat magnetic resonance imaging (MRI: a type of imaging) scan shows amyloid-related imaging abnormalities with edema/effusion (ARIA-E: a type of brain swelling) has resolved or amyloid-related imaging abnormalities with hemorrhage or superficial siderosis (ARIA-H: a type of small bleed in the brain) has stabilized, OR you have asymptomatic (showing no symptoms) mild ARIA with continued MRI monitoring until ARIA-E has resolved or ARIA-H has stabilized

C. If the request is a subsequent renewal request, renewal also requires:

1. You have NOT progressed to moderate or severe Alzheimer's disease (dementia [a type of memory disorder] with moderate to severe functional impairment) as assessed by Mini Mental Status Exam (a test used to evaluate memory, thinking, and understanding) or Clinical Dementia Rating (CDR-SB: a tool for evaluating memory loss) scale and functional status (activities of daily living [ADL: basic everyday tasks] impairment)
2. You will NOT use Kisunla concurrently (at the same time) with any other anti-amyloid medication (such as Leqembi [lecanemab-irmb], Leqembi IQLIK [lecanemab-irmb]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DONANEMAB-AZBT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisunla.

REFERENCES

Kisunla [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; July 2025.

Created: 07/24
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONEPEZIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DONEPEZIL HCL	ADLARITY		52053 52054	GPI-14 (62051025108820, 62051025108830)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of dementia associated with Alzheimer's disease (ICD-10 Group G30) and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to TWO generic oral acetylcholinesterase inhibitors (e.g., donepezil, galantamine)
   - The patient had a trial of or contraindication to ONE generic acetylcholinesterase inhibitor patch (e.g., rivastigmine)

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #4 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DONEPEZIL (Adlarity)** requires the following rule(s) be met for approval:
   A. You have dementia (a type of memory disorder) associated with Alzheimer's disease (a type of brain disorder)
   B. You have tried or have a contraindication to (harmful for you to use) TWO generic oral acetylcholinesterase inhibitors (such as donepezil, galantamine)
   C. You have tried or have a contraindication to (harmful for you to use) ONE generic acetylcholinesterase inhibitor patch (such as rivastigmine)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adlarity.

REFERENCES

Adlarity [Prescribing Information]. Grand Rapids, MI: Astellas Corium, Inc.; March 2022.

Library	Commercial	NSA
Yes	Yes	No

Created: 06/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONIDALORSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DONIDALORSEN SODIUM	DAWNZERA	50832		GPI-10 (8547002070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Dawnzera will be used for prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Dawnzera will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab-gxii])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

3. Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
- The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
- Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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DONIDALORSEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DONIDALORSEN (Dawnzera)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 12 years of age or older
C. Dawnzera will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use Dawnzera concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab- gxii])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONIDALORSEN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?

- The patient has experienced an improvement in HAE attacks (reductions in attack frequency or attack severity) compared to baseline
- Dawnzera will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab-gxii])

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DONIDALORSEN (Dawnzera)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema (a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
C. You will NOT use Dawnzera concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Takhzyro [lanadelumab-flyo], Haegarda [C1 esterase inhibitor], Cinryze [C1 esterase inhibitor], Orladeyo [berotralstat], danazol, Andembry [garadacimab- gxii])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dawnzera.

REFERENCES

Dawnzera [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals Inc.; September 2025.

Created: 09/25
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DONISLECEL-JUJN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DONISLECEL-JUJN	LANTIDRA	49060		GPI-10 (2716082030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 1 diabetes and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is unable to reach their target HbA1c due to current repeated episodes of severe hypoglycemia, despite intensive diabetes management and education
   - The patient has not received a total of 3 doses of Lantidra per lifetime

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 bag for one fill.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DONISLECEL-JUJN (Lantidra)** requires the following rule(s) be met for approval:
   A. You have a diagnosis of type 1 diabetes (a disorder with high blood sugar)
   B. You are 18 years of age or older
   C. You are not able to reach your target hemoglobin A1C (HbA1c: a type of lab test) due to current and repeated episodes of severe hypoglycemia (low blood sugar), despite intensive diabetes management (treatment to control high blood sugar) and education
   D. You have not received a total of 3 doses of Lantidra in your lifetime

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lantidra.

REFERENCES

Lantidra [Prescribing Information]. Chicago, IL: CellTrans Inc.; June 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 03/18/24
Created: 11/23
Client Approval: 03/24
P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DORDAVIPRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DORDAVIPRONE HCL	MODEYSO	50809		GPI-10 (2158001520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of diffuse midline glioma (ICD-10 C71.9) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's tumor has an H3 K27M mutation
   - The patient's disease had progressed following prior therapy (e.g., temozolomide, radiation therapy)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DORDAVIPRONE (Modeyso)** requires the following rule(s) be met for approval:
   A. You have diffuse midline glioma (a type of brain cancer/tumor)
   B. You are 1 year of age or older
   C. Your tumor has an H3 K27M mutation (abnormal change in a type of gene)
   D. Your disease has progressed (worsened) following prior therapy (such as temozolomide, radiation therapy)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Modeyso.

REFERENCES

Modeyso [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; August 2025.

Created: 08/25
Effective: 09/08/25 Client Approval: 08/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DORNASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DORNASE ALFA	PULMOZYME	08832		GPI-10 (4530402000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis (ICD-10 Group E84)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for once daily dosing (30 ampules per month)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.5 mL per day.**
   If no, continue to #3.

3. Has the patient tried once daily dosing (30 ampules per month per MRF or claims history)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 mL per day.**
   If no, do not approve.
   PAC NOTE: Please enter a proactive prior authorization for 12 months by HICL or GPI-10 with a quantity limit of #2.5 mL per day.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DORNASE ALFA (Pulmozyme)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. If you are requesting Pulmozyme (dornase alfa) twice daily dosing, approval also requires:
      1. You have tried and failed Pulmozyme (dornase alfa) once daily dosing

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pulmozyme.

REFERENCE

Pulmozyme [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2024.

Created: 05/12
Effective: 03/04/26 Client Approval: 03/26 P&T Approval: 05/12

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DOSTARLIMAB-GXLY (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DOSTARLIMAB-GXLY	JEMPERLI	47318		GPI-10 (2135792830)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent or advanced endometrial cancer (EC) (ICD-10 C54.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has mismatch repair deficient (dMMR) biomarkers, as determined by an FDA-approved test
   - The patient's cancer has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin)
   - The patient is not a candidate for curative surgery or radiation

   If yes, **approve for 12 months total by HICL or GPI-10 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 3 months with a quantity limit of #10mL per 21 days.**
   - **SECOND APPROVAL: Approve for 9 months with a quantity limit of #20mL per 42 days. (Please enter start date of 5 weeks AFTER the END date of the first approval.)**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #20mL per 42 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of primary advanced or recurrent endometrial cancer (EC) (ICD-10 C54.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Jemperli will be used as a single agent OR in combination with carboplatin and paclitaxel

   If yes, **approve for 12 months total by HICL or GPI-10 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 5 months with a quantity limit of #10mL per 21 days.**
   - **SECOND APPROVAL: Approve for 7 months with a quantity limit of #20mL per 42 days. (Please enter start date of 5 weeks AFTER the END date of the first approval.)**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #20mL per 42 days.**

   If no, continue to #3.

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DOSTARLIMAB-GXLY (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of recurrent or advanced solid tumor and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor has mismatch repair deficient (dMMR) biomarkers, as determined by an FDA-approved test
   - The patient's tumor has progressed on or following prior treatment (e.g., carboplatin, oxaliplatin, irinotecan)
   - The patient has no satisfactory alternative treatment options

   If yes, **approve for 12 months total by HICL or GPI-10 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 3 months with a quantity limit of #10mL per 21 days.**
   - **SECOND APPROVAL: Approve for 9 months with a quantity limit of #20mL per 42 days. (Please enter start date of 5 weeks AFTER the END date of the first approval.)**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #20mL per 42 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DOSTARLIMAB-GXLY (Jemperli)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Recurrent or advanced endometrial cancer (EC: cancer that starts in the lining of the uterus that has returned or has spread from the original site)
      2. Primary advanced or recurrent endometrial cancer
      3. Recurrent or advanced solid tumor

   B. If you have recurrent or advanced endometrial cancer, approval also requires:
      1. You are 18 years of age or older
      2. Your cancer has mismatch repair deficient (dMMR: a type of gene mutation) biomarkers, as determined by a Food and Drug Administration (FDA)-approved test
      3. Your cancer has progressed on or following previous treatment with a platinum-containing regimen (such as carboplatin)
      4. You are not a candidate for curative surgery (cure the disease) or radiation

   (Denial text continued on next page)

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DOSTARLIMAB-GXLY (NSA)

GUIDELINES FOR USE (CONTINUED)

C. If you have primary advanced or recurrent endometrial cancer, approval also requires:
1. You are 18 years of age or older
2. Jemperli will be used as a single agent OR in combination with carboplatin and paclitaxel

D. If you have a recurrent or advanced solid tumor, approval also requires:
1. You are 18 years of age or older
2. Your tumor has mismatch repair deficient (dMMR: a type of gene mutation) biomarkers, as determined by a Food and Drug Administration (FDA)-approved test
3. Your tumor has progressed on or following prior treatment (such as carboplatin, oxaliplatin, irinotecan)
4. You have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Jemperli.

REFERENCES
Jemperli [Prescribing Information]. Philadelphia, PA: GlaxoSmithSkline LLC.; August 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 08/19/24
Created: 07/21
Client Approval: 08/24
P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DOXECITINE-DOXRIBTIMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DOXECITINE/DOXRIBTIMINE	KYGEVVI	50999		GPI-10 (3090990220)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of thymidine kinase 2 deficiency (TK2d) **AND** meet the following criterion?
   - The patient's age at symptom onset for thymidine kinase 2 deficiency (TK2d) is 12 years or younger

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DOXECITINE-DOXRIBTIMINE (Kygevvi)** requires the following rule(s) be met for approval:
   A. You have thymidine kinase 2 deficiency (TK2d: a type of genetic disorder)
   B. Your age at symptom onset for thymidine kinase 2 deficiency (TK2d: a type of genetic disorder) is 12 years or younger

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kygevvi.

REFERENCES

Kygevvi [Prescribing Information]. Smyrna, GA: UCB, Inc.; November 2025.

Created: 06/26
Effective: 07/01/26 Client Approval: 06/26 DMC Approval: 06/16/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DOXYCYCLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DOXYCYCLINE MONOHYDRATE	ORACEA, DOXYCYCLINE IR-DR		27097	GPI-10 (9006002500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of rosacea (ICD-10 Group L71) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has inflammatory lesions (papules and pustules) associated with rosacea
   - The patient had a trial of or contraindication to ONE generic oral minocycline or doxycycline monohydrate/hyclate

   If yes, **approve for 16 weeks by GPID or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DOXYCYCLINE (Oracea, Doxycycline IR-DR)** requires the following rule(s) be met for approval:
   A. You have rosacea (a type of skin condition)
   B. You are 18 years of age or older
   C. You have inflammatory lesions (papules and pustules: small bumps on the skin) associated with rosacea
   D. You have tried or have a contraindication to (harmful for you to use) ONE generic oral minocycline or doxycycline monohydrate/hyclate

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Oracea.

REFERENCES
Oracea [Prescribing Information]. Dallas, TX: Galderma Laboratories, L.P.; April 2025.

Created: 11/24
Effective: 08/04/25 Client Approval: 07/25 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DROXIDOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DROXIDOPA	NORTHERA, DROXIDOPA	40936		GPI-10 (3870003000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neurogenic orthostatic hypotension (nOH) (ICD-10 G90.3) and meet **ALL** of the following criteria?
   - The patient's nOH is caused by ONE of the following: primary autonomic failure (Parkinson's disease [PD], multiple system atrophy, or pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or cardiologist
   - The patient had a trial of or contraindication to midodrine or fludrocortisone
   - The prescriber performed baseline blood pressure readings while the patient is sitting and also within 3 minutes of standing from a supine (lying face up) position
   - The patient has experienced a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within 3 minutes after standing from a sitting position
   - The patient has persistent symptoms of neurogenic orthostatic hypotension, which include dizziness, lightheadedness, and the feeling of 'blacking out'

   If yes, **approve for 1 month by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DROXIDOPA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for approval:

A. You have neurogenic orthostatic hypotension (nOH: a type of low blood pressure)
B. Your condition is caused by primary autonomic failure (Parkinson's disease [PD: a type of movement disorder], multiple system atrophy [a type of nervous system disorder], or pure autonomic failure [a type of nervous system disorder]), dopamine beta-hydroxylase deficiency (type of genetic disorder), or non-diabetic autonomic neuropathy (a type of nerve disorder)
C. You are 18 years of age or older
D. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or cardiologist (a type of heart doctor)
E. You have tried or have a contraindication to (harmful for you to use) midodrine or fludrocortisone
F. Your doctor performed baseline blood pressure readings while you are sitting and also within 3 minutes of standing from a supine (lying face up) position
G. You have experienced a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within 3 minutes after standing from a sitting position
H. You have persistent symptoms of neurogenic orthostatic hypotension, which include dizziness, lightheadedness, and the feeling of 'blacking out'

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DROXIDOPA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neurogenic orthostatic hypotension (nOH) (ICD-10 G90.3) and meet **ALL** of the following criteria?
   - The patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
   - The patient has experienced an increase in systolic blood pressure from baseline of at least 10 mmHg upon standing from a supine (lying face up) position

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for renewal:
   A. You have neurogenic orthostatic hypotension (nOH: a type of low blood pressure)
   B. You have demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like you may black out
   C. You have experienced an increase in systolic blood pressure from baseline of at least 10 mmHg upon standing from a supine (lying face up) position

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Northera.

REFERENCES

Northera [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals LLC; July 2019.

Created: 9/14
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 11/14

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DUPILUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DUPILUMAB	DUPIXENT	44180		GPI-10 (9027302000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 6 months of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Adbry [tralokinumab-ldrm]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Rinvoq [upadacitinib]) and is switching to Dupixent
   - The patient has atopic dermatitis involving at least 10 percent of body surface area (BSA)
   - The patient has atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **ONE** of the following clinical standard of care therapies?
   - Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate)
   - Topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])
   - Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
   - Topical AhR agonist (e.g., Vtama [tapinarof])
   - Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])
   - Phototherapy

   If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the following strengths:**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
   - **200mg/1.14mL: #4.56mL per 28 days.**
   - **300mg/2mL: #8mL per 28 days.)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of moderate to severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient has a pre-treatment blood eosinophil level of 150 to 1500 cells/mcL
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #6.
   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe oral corticosteroid-dependent asthma (ICD-10 J45.909) **AND** meet the following criterion?
   - Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of oral corticosteroid-dependent asthma

   If yes, continue to #6.
   If no, continue to #9.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   - Dupixent will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g., prednisone) burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

   If yes, **approve for 4 months by GPID or GPI-14 for all formulations of the following strengths:**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
   - **200mg/1.14mL: #4.56mL per 28 days.**
   - **300mg/2mL: #8mL per 28 days.)**

   If no, continue to #8.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

8. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 4 months by GPID or GPI-14 for all formulations of the following strengths:**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
   - **200mg/1.14mL: #4.56mL per 28 days.**
   - **300mg/2mL: #8mL per 28 days.)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease
   - The patient had a 56-day trial of ONE clinical standard of care agent: an intranasal corticosteroid (e.g., mometasone nasal spray)
   - Dupixent will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids)
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the 300mg/2mL strength with a quantity limit of #4mL per 28 days.**

   If no, continue to #10.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

10. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ALL** of the following criteria?
- The patient is 1 year of age or older
- The patient weighs at least 15 kg (33 lbs)
- Therapy is prescribed by or in consultation with a gastroenterologist, allergist, or immunologist
- The patient had a trial of or contraindication to dietary therapy
- The patient had a trial of or contraindication to the clinical standard of care agent: a proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole)
- Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EoE

If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the following strengths:**
- **200mg/1.14mL: #2.28mL per 28 days.**
- **300mg/2mL: #8mL per 28 days.**

If no, continue to #11.

11. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist, immunologist, or allergist
- The patient has the presence of multiple pruriginous lesions (localized or general)
- The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (e.g., gabapentin, pregabalin), antidepressants (SNRI, SSRI, TCA), k-/mu-opioid receptor antagonists (e.g., naltrexone, butorphanol), thalidomide, topical corticosteroids, topical calcineurin inhibitors, topical calcipotriol, intralesional corticosteroids, phototherapy, methotrexate, cyclosporine, azathioprine
- Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nemluvio [nemolizumab-ilto]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PN

If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the 300mg/2mL strength with a quantity limit of #4mL per 28 days.**
(Please enter a 1 month approval by GPID or GPI-14 for all formulations of the 300mg/2mL strength with a quantity limit of #8mL per 28 days.)

If no, continue to #12.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

12. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has an eosinophilic phenotype COPD
    - Therapy is prescribed by or in consultation with a pulmonologist
    - The patient has a blood eosinophil level of at least 300 cells/mcL
    - Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere)
    - Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

    If yes, **approve for 4 months by GPID or GPI-14 for all formulations of the 300mg/2mL strength with a quantity limit of #4mL per 28 days.**

    If no, continue to #13.

13. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
    - The patient is 2 years of age or older
    - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
    - The patient still experiences hives or angioedema on most days of the week for at least 6 weeks
    - The patient had a trial of and is maintained on, OR has a contraindication to, 4-times the maximally labeled dose of a second generation H1 antihistamine (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
    - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Xolair [omalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

    If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the following strengths:**
    - **200mg/1.14mL: #2.28mL per 28 days.**
    - **300mg/2mL: #4mL per 28 days.**

    (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
    - **200mg/1.14mL: #4.56mL per 28 days.**
    - **300mg/2mL: #8mL per 28 days.)**

    If no, continue to #14.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

14. Does the patient have a diagnosis of bullous pemphigoid (BP) (ICD-10 L12.0) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the 300mg/2mL strength with a quantity limit of #4mL per 28 days.**
    (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the 300mg/2mL strength with a quantity limit of #8mL per 28 days.)
    - **SUBSEQUENT REQUESTS: Approve for 12 months by GPID or GPI-14 for all formulations of the 300mg/2mL strength with a quantity limit of #4mL per 28 days.**

    If no, continue to #15.

15. Does the patient have a diagnosis of allergic fungal rhinosinusitis (AFRS) (ICD-10 J30.89) and meet **ALL** of the following criteria?
    - The patient is 6 years of age or older
    - The patient has a history of sino-nasal surgery
    - The patient has inadequately controlled disease post endoscopic sinus surgery
    - Therapy is prescribed by or in consultation with an otolaryngologist or allergist/immunologist
    - The patient had a 56-day trial of ONE clinical standard of care agent: an intranasal corticosteroid (e.g., mometasone nasal spray, fluticasone nasal spray, beclomethasone nasal spray)

    If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the following strengths:**
    - **200mg/1.14mL: #2.28mL per 28 days.**
    - **300mg/2mL: #4mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   2. Moderate to severe asthma (a type of lung condition)
   3. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   4. Eosinophilic esophagitis (EoE: a type of immune system disorder)
   5. Prurigo nodularis (PN: a type of skin condition)
   6. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
   7. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]
   8. Bullous pemphigoid (BP: a type of skin condition)
   9. Allergic fungal rhinosinusitis (AFRS: inflammation of nasal and sinus ways due to an allergic reaction to fungi)

B. If you have moderate to severe atopic dermatitis, approval also requires:
   1. You are 6 months of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Adbry [tralokinumab-ldrm]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis
   4. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Rinvoq [upadacitinib]) and are switching to Dupixent
      b. You have atopic dermatitis (a type of skin condition) involving at least 10 percent of body surface area (BSA)
      c. You have atopic dermatitis (a type of skin condition) affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)
   5. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care therapies: topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate), topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus]), topical PDE-4 inhibitor (such as Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast]), topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof]), topical JAK inhibitor (such as Opzelura [ruxolitinib]), phototherapy (light therapy)

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe asthma, approval also requires:

1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
3. You meet ONE of the following:
   a. You have an eosinophilic phenotype asthma (a type of inflammatory asthma) and meet all of the following:
      i. You have a pre-treatment blood eosinophil level (a type of lab test) of 150 to 1500 cells/mcL
      ii. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
   b. You have oral corticosteroid-dependent asthma, AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of oral corticosteroid-dependent asthma
4. Dupixent will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as salmeterol, formoterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline)
5. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

D. If you have chronic rhinosinusitis with nasal polyps, approval also requires:
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
3. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
4. You have inadequately controlled disease
5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray)
6. Dupixent will be used as add-on maintenance treatment (in conjunction [together] with maintenance intranasal steroids [a type of medication used in the nose])
7. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

E. If you have eosinophilic esophagitis, approval also requires:
1. You are 1 year of age or older
2. You weigh at least 15 kilograms (33 pounds)
3. Therapy is prescribed by or in consultation with a gastroenterologist (a type of doctor who treats digestive conditions), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
4. You have tried or have a contraindication to (harmful for you to use) dietary therapy
5. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)
6. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic esophagitis

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

F. If you have prurigo nodularis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
3. You have multiple pruriginous lesions (wounds)
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (such as gabapentin, pregabalin), antidepressants (serotonin-norepinephrine reuptake inhibitor [SNRI], selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant [TCA]), k-/mu-opioid receptor antagonists (such as naltrexone, butorphanol), thalidomide, topical corticosteroids (such as hydrocortisone), topical calcineurin inhibitors (such as Elidel [pimecrolimus]), topical calcipotriol, intralesional corticosteroids, phototherapy (light therapy), methotrexate, cyclosporine, azathioprine
5. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nemluvio [nemolizumab-ilto]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

G. If you have chronic obstructive pulmonary disease, approval also requires:
1. You are 18 years of age or older
2. You have an eosinophilic phenotype chronic obstructive pulmonary disease (COPD) (a type of inflammatory long-term lung condition)
3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
4. You have a blood eosinophil level (a type of lab test) of at least 300 cells/mcL
5. Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
6. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

H. If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
4. You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), 4-times the maximally labeled dose of a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
5. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

I. If you have bullous pemphigoid, approval also requires:
1. You are 18 years of age or older

J. If you have allergic fungal rhinosinusitis, approval also requires:
1. You are 6 years of age or older
2. You have a history of sino-nasal surgery (a type of surgery)
3. You have inadequately controlled disease after endoscopic sinus surgery (a type of surgery)
4. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray, fluticasone nasal spray, beclomethasone nasal spray)

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DUPILUMAB

RENEWAL CRITERIA

NOTE: For the diagnosis of bullous pemphigoid (BP), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on Dupixent
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Adbry [tralokinumab-ldrm]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe asthma with an eosinophilic phenotype (ICD-10 J82.83) **AND** meet the following criterion?
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe oral corticosteroid-dependent asthma (ICD-10 J45.909) **AND** meet the following criterion?
   - Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of oral corticosteroid-dependent asthma

   If yes, continue to #4.
   If no, continue to #6.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

4. Will the patient continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2- agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the 300mg/2mL strength with a quantity limit of #4mL per 28 days.**

   If no, continue to #7.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) (ICD-10 K20.0) and meet **ALL** of the following criteria?
- The patient has shown improvement while on Dupixent (e.g., symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of 6 eos/hpf or less)
- Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EoE

If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
- **200mg/1.14mL: #2.28mL per 28 days.**
- **300mg/2mL: #8mL per 28 days.**

If no, continue to #8.

8. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
- The patient has had prurigo nodularis improvement (reduction) of pruritus or pruriginous lesions
- Dupixent will NOT be used concurrently with another systemic biologic (e.g., Nemluvio [nemolizumab-ilto]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PN

If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the 300mg/2mL strength with a quantity limit of #4mL per 28 days.**

If no, continue to #9.

9. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81) and meet **ALL** of the following criteria?
- The patient has an eosinophilic phenotype COPD
- Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere)
- Dupixent will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

If yes, continue to #10.
If no, continue to #11.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

10. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
    - The patient has a reduction in COPD exacerbations from baseline
    - The patient has a reduction in severity or frequency of COPD-related symptoms (e.g., wheezing, shortness of breath, coughing, sputum production, etc.)
    - The patient has an increase in FEV1 of at least 5 percent from pretreatment baseline

    If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the 300mg/2mL strength with a quantity limit of #4mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

11. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
    - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
    - The patient is maintained on, OR has a contraindication to, a second generation H1 antihistamine (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
    - Dupixent will NOT be used concurrently with another systemic biologic (e.g., Xolair [omalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

    If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
    - **200mg/1.14mL: #2.28mL per 28 days.**
    - **300mg/2mL: #4mL per 28 days.**

    If no, continue to #12.

12. Does the patient have a diagnosis of allergic fungal rhinosinusitis (AFRS) (ICD-10 J30.89) **AND** meet the following criterion?
    - The patient has shown clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)

    If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
    - **200mg/1.14mL: #2.28mL per 28 days.**
    - **300mg/2mL: #4mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   2. Moderate to severe asthma (a type of lung condition)
   3. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   4. Eosinophilic esophagitis (EoE: a type of immune system disorder)
   5. Prurigo nodularis (PN: a type of skin condition)
   6. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
   7. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]
   8. Allergic fungal rhinosinusitis (AFRS: inflammation of nasal and sinus ways due to an allergic reaction to fungi)

B. If you have moderate to severe atopic dermatitis, renewal also requires:
   1. You have shown improvement while on Dupixent
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Adbry [tralokinumab-ldrm]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

C. If you have moderate to severe asthma, renewal also requires:

1. You meet ONE of the following:
   a. You have an eosinophilic phenotype asthma (a type of inflammatory asthma), AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
   b. You have oral corticosteroid-dependent asthma, AND you will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of oral corticosteroid-dependent asthma
2. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) (such as a long-acting inhaled beta2-agonist [such as salmeterol, formoterol], a long-acting muscarinic antagonist [such as Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [such as montelukast, zafirlukast], theophylline)
3. You have shown a clinical response as evidenced by ONE of the following:
   a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Dupixent)
   b. You have decreased your use of rescue medications (such as albuterol)
   c. You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Dupixent)
   d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

D. If you have chronic rhinosinusitis with nasal polyps, renewal also requires:

1. You have shown a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell, size of polyps)
2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

E. **If you have eosinophilic esophagitis, renewal also requires**:
   1. You have shown improvement while on Dupixent (such as symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of 6 eos/hpf or less [a type of test that evaluates disease status])
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic esophagitis

F. If you have prurigo nodularis, renewal also requires:
   1. You have had prurigo nodularis improvement or reduction of pruritus (itching) or pruriginous lesions (wounds)
   2. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Nemluvio [nemolizumab-ilto]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis

G. If you have chronic obstructive pulmonary disease, renewal also requires:
   1. You have an eosinophilic phenotype chronic obstructive pulmonary disease (COPD) (a type of inflammatory long-term lung condition)
   2. Dupixent will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
   3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD
   4. You have shown a clinical response as evidenced by ONE of the following:
      a. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Dupixent)
      b. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum [mucus] production)
      c. You have had an increase in FEV1 (a type of lung test) by at least 5 percent from pretreatment baseline (before starting Dupixent)

(Renewal denial text continued on next page)

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

H. If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:
1. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
2. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
3. You will NOT use Dupixent concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

I. If you have allergic fungal rhinosinusitis, renewal also requires:
1. You have shown a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell, size of polyps)

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Dupixent.

REFERENCES

Dupixent [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; February 2026.

Created: 01/17
Effective: 07/15/26 DMC Approval: 06/29/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DURVALUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DURVALUMAB	IMFINZI	44230		GPI-10 (2135822900)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
- The patient is 18 years of age or older

If yes, continue to #2.
If no, continue to #5.

2. Does the patient have resectable (node positive or tumors are at least 4 cm) cancer and meet **ALL** of the following criteria?
- The patient has no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements
- Imfinzi will be used in combination with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery and prior use in combination with platinum-containing chemotherapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

3. Does the patient have unresectable Stage III cancer **AND** meet the following criterion?
- The patient's disease has NOT progressed following concurrent platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

4. Does the patient have metastatic cancer and meet **ALL** of the following criteria?
- The patient does NOT have sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
- Imfinzi will be used in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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DURVALUMAB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of small cell lung cancer (SCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #6.
   If no, continue to #8.

6. Does the patient have limited-stage (LS) cancer **AND** meet the following criterion?
   - The patient's disease has NOT progressed following concurrent platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient have extensive-stage (ES) cancer **AND** meet the following criterion?
   - Imfinzi will be used in combination with etoposide, AND either carboplatin or cisplatin

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

8. Does the patient have a diagnosis of locally advanced or metastatic biliary tract cancer (BTC) (ICD-10 Group C24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Imfinzi will be used in combination with gemcitabine and cisplatin

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

9. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (uHCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Imfinzi will be used in combination with Imjudo (tremelimumab-actl)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #10.

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DURVALUMAB

GUIDELINES FOR USE (CONTINUED)

10. Does the patient have a diagnosis of primary advanced or recurrent endometrial cancer (ICD-10 C54.1) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's cancer is mismatch repair deficient (dMMR), as determined by an FDA-approved test
    - Imfinzi will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #11.

11. Does the patient have a diagnosis of high-risk non-muscle invasive bladder cancer (NMIBC) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient is Bacillus Calmette-Guérin (BCG) naive
    - Imfinzi will be used in combination with Bacillus Calmette-Guérin (BCG)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #12.

12. Does the patient have a diagnosis of muscle invasive bladder cancer (MIBC) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Imfinzi will be used in combination with gemcitabine and cisplatin as neoadjuvant treatment, OR as a single agent as adjuvant treatment following radical cystectomy and prior use in combination with gemcitabine and cisplatin

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #13.

13. Does the patient have a diagnosis of resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC) (ICD-10 Group C16) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Imfinzi will be used in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, OR as a single-agent after prior use in combination with FLOT

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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DURVALUMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DURVALUMAB (Imfinzi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-small cell lung cancer (NSCLC: a type of lung cancer)
   2. Small cell lung cancer (SCLC: a type of lung cancer)
   3. Locally advanced or metastatic biliary tract cancer (a type of biliary tract cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
   4. Unresectable hepatocellular carcinoma (a type of liver cancer that cannot be completely removed by surgery)
   5. Primary advanced or recurrent endometrial cancer (a type of uterus cancer that has spread or has returned after treatment)
   6. High-risk non-muscle invasive bladder cancer (NMIBC: bladder cancer that has not spread to the muscles)
   7. Muscle invasive bladder cancer (MIBC: bladder cancer that has spread to the muscles)
   8. Resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC) (a type of digestive system cancer that can be removed by surgery)

B. If you have non-small cell lung cancer, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Your cancer is resectable (can be removed by surgery) (node positive [has spread to the lymph nodes] or tumors are at least 4 cm); you have no known epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements; and Imfinzi will be used in combination with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant treatment (additional treatment) after surgery and previous use in combination with platinum-containing chemotherapy
      b. Your cancer is Stage III and unresectable (cannot be completely removed by surgery); and your disease has NOT progressed (worsened) after using concurrent (at the same time) platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT: concurrent chemoradiotherapy)
      c. Your cancer is metastatic (cancer that has spread to other parts of the body); you do NOT have sensitizing epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (a type of abnormal gene); and Imfinzi will be used in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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DURVALUMAB

GUIDELINES FOR USE (CONTINUED)

C. If you have small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have limited-stage cancer (LS: cancer that is contained in a single area on one side of the chest) AND your disease has NOT progressed (worsened) following concurrent (at the same time) platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy (cCRT: concurrent chemoradiotherapy)
   b. You have extensive-stage cancer (ES: cancer that has spread widely throughout the lungs or other parts of the body) and Imfinzi will be used in combination with etoposide, AND either carboplatin or cisplatin

D. If you have locally advanced or metastatic biliary tract cancer, approval also requires:
1. You are 18 years of age or older
2. Imfinzi will be used in combination with gemcitabine and cisplatin

E. If you have unresectable hepatocellular carcinoma, approval also requires:
1. You are 18 years of age or older
2. Imfinzi will be used in combination with Imjudo (tremelimumab-actl)

F. If you have primary advanced or recurrent endometrial cancer, approval also requires:
1. You are 18 years of age or older
2. Your cancer is mismatch repair deficient (dMMR: a type of gene mutation [abnormal change]), as determined by a Food and Drug Administration (FDA)-approved test
3. Imfinzi will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

G. If you have high-risk non-muscle invasive bladder cancer, approval also requires:
1. You are 18 years of age or older
2. You are Bacillus Calmette-Guérin (BCG: a type of bladder cancer treatment) naive (have not previously used BCG)
3. You will use Imfinzi in combination with Bacillus Calmette-Guérin (BCG)

H. If you have muscle invasive bladder cancer, approval also requires:
1. You are 18 years of age or older
2. Imfinzi will be used in combination with gemcitabine and cisplatin as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant treatment (additional treatment) following radical cystectomy (bladder removal surgery) and previous use in combination with gemcitabine and cisplatin

I. If you have resectable gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Imfinzi will be used in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant (given before main treatment) and adjuvant (add-on) treatment, OR as a single-agent after prior use in combination with FLOT

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DURVALUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imfinzi.

REFERENCES

Imfinzi [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.

Created: 08/17
Effective: 06/17/26 Client Approval: 06/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DUVELISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DUVELISIB	COPIKTRA	45269		GPI-10 (2153803000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least two prior therapies for CLL or SLL

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **DUVELISIB (Copiktra)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Relapsed or refractory chronic lymphocytic leukemia (CLL: a type of blood cancer that has returned after treatment or did not fully respond to treatment)
      2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
   B. You are 18 years of age or older
   C. You have received at least two prior therapies for chronic lymphocytic leukemia or small lymphocytic lymphoma

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Copiktra.

REFERENCES

Copiktra [Prescribing Information]. Las Vegas, NV: Secura Bio, Inc.; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/18
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECALLANTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ECALLANTIDE	KALBITOR	36797		GPI-10 (8584003000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Kalbitor will be used for the treatment of acute attacks of hereditary angioedema
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Kalbitor will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and/or angioedema
- Kalbitor will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Firazyr [icatibant])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for 12 months (up to 12 fills) by HICL or GPI-10 with a quantity limit of #12mL per fill.**
If no, continue to #3.

3. Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
- The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
- Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

If yes, **approve for 12 months (up to 12 fills) by HICL or GPI-10 with a quantity limit of #12mL per fill.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ECALLANTIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ECALLANTIDE (Kalbitor)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 12 years of age or older
C. Kalbitor will be used for the treatment of acute (sudden and severe) attacks of hereditary angioedema (HAE: a type of gene condition with severe body swelling)
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. Kalbitor will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis (severe, possible life-threatening allergic reaction) and/or angioedema (a type of swelling)
F. You will NOT use Kalbitor concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Firazyr [icatibant])
G. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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ECALLANTIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?

- The patient has experienced a reduction in the severity or duration of HAE attacks
- Kalbitor will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Firazyr [icatibant])

If yes, **approve for 12 months (up to 12 fills) by HICL or GPI-10 with a quantity limit of #12mL per fill.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ECALLANTIDE (Kalbitor)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced a reduction (decrease) in the severity or duration of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
C. You will NOT use Kalbitor concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Firazyr [icatibant])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kalbitor.

REFERENCES

Kalbitor [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; June 2025.

Created: 11/13
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ECULIZUMAB	SOLIRIS	34618		GPI-10 (8580505000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC- HUS) (ICD-10 D59.31)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent
   - The patient has tried and failed (as evidenced by hemoglobin levels less than 10.5 g/dL directly following at least 3 months of stable dosing) or has a contraindication to Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)
   - Soliris will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #240mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #180mL per 28 days (please enter a start date of 1 day after the end date of the first approval).**

   If no, continue to #3.

3. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+)
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - Soliris will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG

   If yes, continue to #5.
   If no, continue to #7.

5. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age
   - The patient is 18 years of age or older AND had a trial of or contraindication to ONE of the following preferred agents: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa- fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #360mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #240mL per 28 days (please enter a start date of 1 day after the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ophthalmologist
   - The patient is positive for anti-aquaporin-4 (AQP4) antibodies
   - The patient had a trial of or contraindication to the preferred agent: Ultomiris (ravulizumab-cwvz)
   - Soliris will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Does the patient have at least **ONE** of the following core clinical characteristics?
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #360mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #240mL per 28 days (please enter a start date of 1 day after the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   2. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
   3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   4. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

B. Soliris (eculizumab) is NOT being used for the treatment of hemolytic uremic syndrome related to Shiga toxin E. coli (a bacteria)

C. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
   4. You have tried and failed (as shown by hemoglobin [Hgb: a type of protein in red blood cells] levels less than 10.5 g/dL immediately following at least 3 months of stable dosing) or have a contraindication to (harmful for you to use) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)
   5. You will NOT use Soliris concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

D. If you have generalized myasthenia gravis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
3. You have a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+: a type of blood test that shows you have myasthenia gravis)
4. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
5. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
6. You will NOT use Soliris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
7. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
   b. You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)
8. If you are 18 years of age or older, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)

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ECULIZUMAB

INITIAL CRITERIA (CONTINUED)

E. If you have neuromyelitis optica spectrum disorder, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
3. You have a positive test for anti-aquaporin-4 (AQP4: a type of protein) antibodies
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ultomiris (ravulizumab-cwvz)
5. You will NOT use Soliris concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])
6. You have at least ONE of the following core clinical characteristics:
   a. Optic neuritis (a type of brain disorder)
   b. Acute myelitis (a type of brain disorder)
   c. Area postrema syndrome (a type of brain disorder)
   d. Acute brainstem syndrome (a type of brain disorder)
   e. Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
   f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline
   - Soliris will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient experienced a clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Soliris will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #240mL per 28 days.**
   If no, continue to #4.

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ECULIZUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient experienced a reduction in relapse frequency compared to baseline
   - Soliris will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #240mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      2. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
      3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
      4. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

   B. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
      1. You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before treatment)
      2. You will NOT use Soliris concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

   C. If you have generalized myasthenia gravis, renewal also requires:
      1. You have experienced a clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
      2. You will NOT use Soliris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

   (Renewal denial text continued on next page)

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ECULIZUMAB

RENEWAL CRITERIA (CONTINUED)

D. If you have neuromyelitis optica spectrum disorder, renewal also requires:

1. You have experienced a reduction in relapse frequency compared to baseline (before treatment)
2. You will NOT use Soliris concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Soliris.

REFERENCES

Soliris [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; February 2025.

Created: 08/13
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB-AAGH

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ECULIZUMAB-AAGH	EPYSQLI	49759		GPI-10 (8580505002)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC- HUS) (ICD-10 D59.31)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent
   - The patient has tried and failed (as evidenced by hemoglobin levels less than 10.5 g/dL directly following at least 3 months of stable dosing) or has a contraindication to Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)
   - Epysqli will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #240mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #180mL per 28 days (please enter a start date of 1 day after the end date of the first approval).**

   If no, continue to #3.

3. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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ECULIZUMAB-AAGH

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+)
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - Epysqli will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG

   If yes, continue to #5.
   If no, continue to #7.

5. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age
   - The patient is 18 years of age or older AND had a trial of or contraindication to ONE of the following preferred agents: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa- fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #360mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #240mL per 28 days (please enter a start date of 1 day after the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ECULIZUMAB-AAGH

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ophthalmologist
   - The patient is positive for anti-aquaporin-4 (AQP4) antibodies
   - The patient had a trial of or contraindication to the preferred agent: Ultomiris (ravulizumab-cwvz)
   - Epysqli will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Does the patient have at least **ONE** of the following core clinical characteristics?
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #360mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #240mL per 28 days (please enter a start date of 1 day after the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ECULIZUMAB-AAGH

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ECULIZUMAB-AAGH (Epysqli)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   2. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
   3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   4. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

B. Epysqli (eculizumab-aagh) is NOT being used for the treatment of hemolytic uremic syndrome related to Shiga toxin E. coli (a bacteria)

C. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
   4. You have tried and failed (as shown by hemoglobin [Hgb: a type of protein in red blood cells] levels less than 10.5 g/dL immediately following at least 3 months of stable dosing) or have a contraindication to (harmful for you to use) Fabhalta (iptacopan) or Ultomiris (ravulizumab-cwvz)
   5. You will NOT use Epysqli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

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ECULIZUMAB-AAGH

INITIAL CRITERIA (CONTINUED)

D. If you have generalized myasthenia gravis, approval also requires:

1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
3. You have a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+: a type of blood test that shows you have myasthenia gravis)
4. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
5. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
6. You will NOT use Epysqli concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
7. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
   b. You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)
8. If you are 18 years of age or older, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)

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ECULIZUMAB-AAGH

INITIAL CRITERIA (CONTINUED)

E. If you have neuromyelitis optica spectrum disorder, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
3. You have a positive test for anti-aquaporin-4 (AQP4: a type of protein) antibodies
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ultomiris (ravulizumab-cwvz)
5. You will NOT use Epysqli concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])
6. You have at least ONE of the following core clinical characteristics:
   a. Optic neuritis (a type of brain disorder)
   b. Acute myelitis (a type of brain disorder)
   c. Area postrema syndrome (a type of brain disorder)
   d. Acute brainstem syndrome (a type of brain disorder)
   e. Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
   f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ECULIZUMAB-AAGH

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline
   - Epysqli will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient experienced a clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Epysqli will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #240mL per 28 days.**

   If no, continue to #4.

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ECULIZUMAB-AAGH

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient experienced a reduction in relapse frequency compared to baseline
   - Epysqli will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #240mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ECULIZUMAB-AAGH (Epysqli)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      2. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
      3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
4. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

   B. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
      1. You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before treatment)
      2. You will NOT use Epysqli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

   C. If you have generalized myasthenia gravis, renewal also requires:
      1. You have experienced a clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
      2. You will NOT use Epysqli concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

(Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. If you have neuromyelitis optica spectrum disorder, renewal also requires:
1. You have experienced a reduction in relapse frequency compared to baseline (before treatment)
2. You will NOT use Epysqli concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Epysqli and Soliris.

REFERENCES

Epysqli [Prescribing Information]. Incheon, South Korea: Samsung Bioepis Co.; April 2025.
Soliris [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; February 2025.

Created: 04/25
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 10/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EDARAVONE	RADICAVA, EDARAVONE	44252		GPI-10 (7450903000)	ROUTE = INTRAVEN.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** of the following?
   - Therapy is prescribed by or in consultation with a neurologist or ALS specialist at an ALS Specialty Center or Care Clinic
   - The patient's duration of disease (from onset of symptoms) is 2 years or less
   - The patient has normal respiratory function (e.g., Forced Vital Capacity [FVC] at least 80 percent)
   - The patient has mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, respiratory insufficiency
   - The patient has tried riluzole OR is currently taking riluzole

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the requested strength for 1 month as follows:**
     - **30mg/100mL: #2800mL per 28 days for 1 fill.**
     - **60mg/100mL: #1400mL per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (please enter a start date of TWO days before the end of the first approval):**
     - **30mg/100mL: #2000mL per 28 days.**
     - **60mg/100mL: #1000mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EDARAVONE (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EDARAVONE (Radicava)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ALS specialist at an ALS Specialty Center or Care Clinic
C. You have had the disease (from onset of symptoms) for 2 years or less
D. You have normal respiratory (breathing) function (such as Forced Vital Capacity [FVC: a type of lung test] of at least 80 percent)
E. You have mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)
F. You have tried riluzole OR are currently taking riluzole

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EDARAVONE (NSA)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** of the following criteria?
   - The patient does not require invasive ventilation
   - The patient has improved baseline functional ability as measured by Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) OR the patient has maintained a score of 2 or greater in all 12 items of ALSFRS-R

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **30mg/100mL: #2000mL per 28 days.**
   - **60mg/100mL: #1000mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EDARAVONE (Radicava)** requires the following rule(s) be met for renewal:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You do not require invasive ventilation (inserting a breathing tube into the throat)
   C. You have improved baseline functional ability as measured by Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R: a tool for evaluating functional status) OR you have maintained a score of 2 or greater in all 12 items of ALSFRS-R

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EDARAVONE (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Radicava.

REFERENCES

Radicava [prescribing information]. Jersey City, NJ: Mitsubishi Tanabe Pharma America, Inc.; November 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 08/17
Client Approval: 06/24
P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE ORAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EDARAVONE	RADICAVA ORS		52318	GPI-14 (74509030001820)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** the following?
   - Therapy is prescribed by or in consultation with a neurologist or ALS specialist at an ALS Specialty Center or Care Clinic
   - The duration of patient's disease (from onset of symptoms) is 2 years or less
   - The patient has a forced vital capacity (FVC) of at least 80%
   - The patient has mild to moderate ALS with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, respiratory insufficiency
   - The patient has tried the clinical standard of care agent riluzole OR is currently taking riluzole

   If yes, **enter two approvals by GPID or GPI-14 for a total of 6 months as follows:**
   - **FIRST APPROVAL: Approve for 30 days with a quantity limit of #70mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #50mL per 28 days (Enter a start date of 2 days before the end of the first approval).**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or an amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition) specialist at an ALS Specialty Center or Care Clinic
   C. You have had amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition) (from onset of symptoms) for 2 years or less
   D. You have a forced vital capacity (FVC: amount of air exhaled from lungs) of at least 80%
   E. You have tried the clinical standard of care medication riluzole OR are currently taking riluzole

   (Initial denial text continued on next page)

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EDARAVONE ORAL

INITIAL CRITERIA (CONTINUED)

F. You have mild to moderate amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition) with a score of 2 or higher in all of the following 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R: a tool for evaluating functional status): speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea (difficulty breathing), orthopnea (shortness of breath while lying down), respiratory insufficiency (a type of breathing condition)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EDARAVONE ORAL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** of the following criteria?
   - The patient does not require invasive ventilation
   - The patient has improved baseline functional ability OR the patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #50mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EDARAVONE ORAL (Radicava ORS)** requires the following rule(s) be met for renewal:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You do not require invasive ventilation (inserting a breathing tube into the throat)
   C. You have improved baseline functional ability OR you have maintained a score of 2 or greater in all 12 items of the Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R: a tool for evaluating functional status)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Radicava ORS.

REFERENCES

Radicava ORS [Prescribing Information]. Jersey City, NJ: Tanabe Pharma America, Inc.; December 2025.

Created: 05/22
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFBEMALENOGRASTIM ALFA-VUXW

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFBEMALENOGRASTIM ALFA-VUXW	RYZNEUTA	49318		GPI-10 (8240151680)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFBEMALENOGRASTIM ALFA-VUXW (Ryzneuta)** requires the following rule(s) be met for approval:
   A. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   B. You are 18 years of age or older
   C. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   E. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ryzneuta.

REFERENCES

Ryzneuta [Prescribing Information]. East Windsor, NJ: Acrotech Biopharma Inc; December 2024.

Created: 05/25
Effective: 06/01/25 Client Approval: 05/25 P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFLAPEGRASTIM-XNST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFLAPEGRASTIM-XNST	ROLVEDON	48301		GPI-10 (8240151880)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred agent: Ziextenzo (pegfilgrastim-bmez)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFLAPEGRASTIM-XNST (Rolvedon)** requires the following rule(s) be met for approval:
   A. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   B. You are 18 years of age or older
   C. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   D. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   E. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ziextenzo (pegfilgrastim-bmez)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rolvedon.

REFERENCES

Rolvedon [Prescribing Information]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; June 2023.

Created: 10/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EFLORNITHINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EFLORNITHINE HCL	IWILFIN	21417		GPI-10 (2175722030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of high-risk neuroblastoma (HRNB) **AND** meet the following criterion?
   - The patient has demonstrated a partial response to prior therapy, including anti-GD2 immunotherapy (e.g., Unituxin [dinutuximab])

   If yes, **approve for 24 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EFLORNITHINE (Iwilfin)** requires the following rule(s) be met for approval:
   A. You have high-risk neuroblastoma (HRNB: a type of rare cancer)
   B. You have shown a partial response (the cancer partly responded to treatment, but still did not go away) to prior therapy, including anti-GD2 immunotherapy (such as Unituxin [dinutuximab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iwilfin.

REFERENCES

Iwilfin [Prescribing Information]. Louisville, KY: US WorldMeds, LLC.; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/15/24
Created: 12/23
Client Approval: 12/23
P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELACESTRANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELACESTRANT HCL	ORSERDU	48658		GPI-10 (2140372010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's breast cancer is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor-1 (ESR1) gene mutation(s) as detected by an FDA-authorized test
   - The patient has had disease progression following at least ONE line of endocrine therapy (e.g., anastrozole, letrozole)
   - Therapy is prescribed by or in consultation with an oncology specialist
   - Orserdu will NOT be used concurrently with another selective estrogen receptor degrader (SERD) (e.g., Veppanu [vepdegestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **345 mg: #1 per day.**
   - **86 mg: #3 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT:

   Our guideline named **ELACESTRANT (Orserdu)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. Your breast cancer is estrogen receptor (ER: type of protein)-positive, human epidermal growth factor receptor 2 (HER2: type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test
   C. You have had disease progression (worsening) following at least ONE line of endocrine therapy (a type of hormone therapy such as anastrozole, letrozole)
   D. Therapy is prescribed by or in consultation with an oncology specialist (a type of cancer doctor)
   E. You will NOT use Orserdu concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Veppanu [vepdegestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELACESTRANT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's breast cancer is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor-1 (ESR1) gene mutation(s) as detected by an FDA-authorized test
   - The patient has demonstrated clinical benefit while on therapy as shown by a partial or complete response OR stable disease
   - Orserdu will NOT be used concurrently with another selective estrogen receptor degrader (SERD) (e.g., Veppanu [vepdegestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **345 mg: #1 per day.**
   - **86 mg: #3 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **ELACESTRANT (Orserdu)** requires the following rule(s) be met for renewal:
   A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. Your breast cancer is estrogen receptor (ER: type of protein)-positive, human epidermal growth factor receptor 2 (HER2: type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test
   C. You have experienced clinical benefit while on therapy as shown by a partial (cancer has shrunk but did not go away) or complete response (cancer went away completely) OR stable disease (disease has stopped growing or spreading)
   D. You will NOT use Orserdu concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Veppanu [vepdegestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Orserdu.

REFERENCES
Orserdu [Prescribing Information]. New York, NY: Stemline Therapeutics, Inc.; June 2026.

Created: 05/23
Effective: 08/21/26 Client Approval: 08/26 DMC Approval: 08/11/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAFIBRANOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAFIBRANOR	IQIRVO	49672		GPI-10 (5278002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) as confirmed by at least **TWO** of the following criteria?
   - The patient has an elevated alkaline phosphatase (ALP) level
   - The patient has antimitochondrial antibodies (AMA) OR has other PBC-specific autoantibodies, including sp100 or gp210 if AMA is negative
   - The patient has histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist or hepatologist
   - The patient does NOT have decompensated cirrhosis (Child-Pugh B or C)
   - Iqirvo will NOT be used concurrently with any other second-line PBC treatment (Ocaliva [obeticholic acid], Livdelzi [seladelpar])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - Iqirvo will be used as monotherapy in a patient who is unable to tolerate ursodiol (UDCA: ursodeoxycholic acid)
   - Iqirvo will be used in combination with ursodiol (UDCA: ursodeoxycholic acid) in a patient who had an inadequate response to at least 1 year of treatment with ursodiol (UDCA: ursodeoxycholic acid) monotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAFIBRANOR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAFIBRANOR (Iqirvo)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
   1. You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   2. You have antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or you have other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210 if AMA is negative
   3. You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)

B. You are 18 years of age or older

C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)

D. You do NOT have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage)

E. You will NOT use Iqirvo concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Livdelzi [seladelpar])

F. You meet ONE of the following:
   1. Iqirvo will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (UDCA: ursodeoxycholic acid)
   2. Iqirvo will be used in combination (together) with ursodiol (UDCA: ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (UDCA: ursodeoxycholic acid) monotherapy (one drug treatment)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELAFIBRANOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) and meet **ALL** of the following criteria?
   - The patient has an alkaline phosphatase (ALP) level that is less than 1.67 -times the upper limit of normal AND which has decreased by at least 15% from baseline while on treatment with Iqirvo
   - Iqirvo will NOT be used concurrently with any other second-line PBC treatment (Ocaliva [obeticholic acid], Livdelzi [seladelpar])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAFIBRANOR (Iqirvo)** requires the following rule(s) be met for renewal:
   A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
   B. You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67- times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Iqirvo
   C. You will NOT use Iqirvo concurrently (at the same time) with any other second-line therapy for PBC (Ocaliva [obeticholic acid], Livdelzi [seladelpar])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iqirvo.

REFERENCES

Iqirvo [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; June 2024.

Created: 06/24
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAGOLIX SODIUM	ORILISSA	45108		GPI-10 (3009003010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient previously received **ONE** of the following regimens?
   - A 6-month course of Orilissa 200 mg twice daily
   - A 6-month course of Orilissa 150 mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
   - A 24-month course of Orilissa 150 mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis (ICD-10 R52 and Group N80) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - Orilissa will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have moderate hepatic impairment (Child-Pugh Class B)?

   If yes, **approve 150 mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, continue to #4.

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ELAGOLIX

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following?
   - The patient has normal liver function
   - The patient has mild hepatic impairment (Child-Pugh Class A)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **150 mg: #1 per day.**
   - **200 mg: #2 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:
   A. You have moderate to severe pain associated with endometriosis (condition affecting the uterus)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   D. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
   E. You have normal liver function, or mild to moderate hepatic (liver) impairment (Child-Pugh Class A or B: a tool for evaluating severity of liver damage)
   F. Requests for Orilissa 200 mg twice daily will only be approved if you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)
   G. Requests will not be approved if you have previously received ONE of the following:
      1. A 6-month course of Orilissa 200 mg twice daily
      2. A 6-month course of Orilissa 150 mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
      3. A 24-month course of Orilissa 150 mg once daily and you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

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ELAGOLIX

RENEWAL CRITERIA

1. Has the patient previously received **ONE** of the following regimens?
   - A 6-month course of Orilissa 200 mg twice daily
   - A 6-month course of Orilissa 150 mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
   - A 24-month course of Orilissa 150 mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis (ICD-10 R52 and Group N80) and meet **ALL** of the following criteria?
   - The patient has improvement of pain related to endometriosis while on therapy
   - The patient has normal liver function OR mild hepatic impairment (Child-Pugh Class A)
   - Orilissa will NOT be used concurrently with another GnRH-modulating agent (e.g., Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])

   If yes, **approve 150 mg for 18 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe pain associated with endometriosis (condition affecting the uterus)
   B. You have improvement of pain related to endometriosis while on therapy
   C. You have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)
   D. Orilissa will NOT be used at the same time with another GnRH-modulating agent (such as Lupron Depot [leuprolide], Synarel [nafarelin], Zoladex [goserelin])
   E. Requests will not be approved if you have previously received ONE of the following:
      1. A 6-month course of Orilissa 200 mg twice daily
      2. A 6-month course of Orilissa 150 mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
      3. A 24-month course of Orilissa 150 mg once daily and you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

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ELAGOLIX

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orilissa.

REFERENCES

Orilissa [Prescribing Information]. North Chicago, IL: AbbVie Inc.; June 2023.

Created: 08/18
Effective: 08/07/26 Client Approval: 08/26 DMC Approval: 08/04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX/ESTRADIOL/NORETHINDRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAGOLIX/ESTRADIOL /NORETHINDRONE	ORIAHNN	46577		GPI-10 (2499350340)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) (ICD-10 Group D25) and the patient meets **ALL** of following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an OB/GYN
   - Oriahnn will NOT be used concurrently with another GnRH-modulating agent (e.g., Myfembree [relugolix/estradiol/norethindrone], Lupron Depot [leuprolide])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for approval:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You are 18 years of age or older
   C. You are a premenopausal (before menopause) woman
   D. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   E. You will NOT use Oriahnn concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Myfembree [relugolix/estradiol/norethindrone], Lupron Depot [leuprolide])
   F. You have not received a total of 24 months cumulative treatment with Oriahnn

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX/ESTRADIOL/NORETHINDRONE

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Oriahnn?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) (ICD-10 Group D25) and the patient meets **ALL** of the following criteria?
   - The patient has had improvement of heavy menstrual bleeding
   - Oriahnn will NOT be used concurrently with another GnRH-modulating agent (e.g., Myfembree [relugolix/estradiol/norethindrone], Lupron Depot [leuprolide])

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #2 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (Oriahnn)** requires the following rule(s) be met for renewal:
   A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   B. You have had improvement of heavy menstrual bleeding on therapy
   C. You will NOT use Oriahnn concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Myfembree [relugolix/estradiol/norethindrone], Lupron Depot [leuprolide])
   D. You have not received a total of 24 months cumulative treatment with Oriahnn

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oriahnn.

REFERENCES

Oriahnn [Prescribing Information]. North Chicago, IL: AbbVie Inc.; December 2025.

Created: 08/20
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAMIPRETIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAMIPRETIDE HCL	FORZINITY	50903		GPI-10 (3090833020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Barth syndrome (ICD-10 E78.71) **AND** meet the following criterion?
   - The patient weighs at least 30 kg (66 lbs)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAMIPRETIDE (Forzinity)** requires the following rule(s) be met for approval:
   A. You have Barth syndrome (a rare genetic condition)
   B. You weigh at least 30 kilograms (66 pounds)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Forzinity.

REFERENCES

Forzinity [Prescribing Information]. Needham, MA: Stealth BioTherapeutics Inc.; September 2025.

Created: 10/25
Effective: 10/20/25 Client Approval: 10/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAPEGADEMASE-LVLR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAPEGADEMASE-LVLR	REVCOVI	45340		GPI-10 (3090203020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) (ICD-10 D81.31) as manifested by **ONE** of the following criteria?
   - The patient has a confirmatory genetic test
   - The patient has suggestive laboratory findings (e.g., elevated deoxyadenosine nucleotide [dAXP] levels, lymphopenia) AND hallmark signs/symptoms (e.g., recurrent infections, failure to thrive, persistent diarrhea)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is therapy prescribed by or in consultation with an immunologist, hematologist-oncologist, or physician specializing in inherited metabolic disorders?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has failed or is NOT a candidate for hematopoietic cell transplantation (HCT)
   - Revcovi will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ELAPEGADEMASE-LVLR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for approval:

A. You have adenosine deaminase severe combined immune deficiency (ADA-SCID: an inherited disorder that damages the immune system) as shown by ONE of the following:
   1. You have a confirmatory genetic test
   2. You have suggestive laboratory findings (such as elevated deoxyadenosine nucleotide levels, lymphopenia [low levels of a type of white blood cell]) AND you have hallmark signs/symptoms (such as recurrent infections, failure to thrive, persistent diarrhea)

B. Therapy is prescribed by or in consultation with an immunologist (a type of immune system doctor), hematologist-oncologist (a type of blood-cancer doctor), or physician specializing in inherited metabolic disorders

C. You meet ONE of the following:
   1. You have failed or are not a candidate for hematopoietic cell transplant (blood cell transplant from bone marrow)
   2. Revcovi will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELAPEGADEMASE-LVLR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) (ICD-10 D81.31) and meet **ALL** of the following criteria?
   - The patient has a trough plasma adenosine deaminase (ADA) activity of at least 30 mmol/hr/L AND trough deoxyadenosine nucleotide (dAXP) levels less than 0.02 mmol/L
   - The patient has improvement in or maintenance of immune function from baseline (e.g., decrease in number and severity of infections)
   - The patient has NOT received a successful hematopoietic cell transplantation (HCT) or gene therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for renewal:
   A. You have adenosine deaminase severe combined immune deficiency (ADA-SCID: an inherited disorder that damages the immune system)
   B. You have a trough plasma adenosine deaminase (ADA) activity of at least 30 mmol/hr/L AND trough deoxyadenosine nucleotide (dAXP) levels less than 0.02 mmol/L
   C. You have shown improvement in or maintenance of immune function from baseline (such as a decrease in the number and severity of infections)
   D. You have NOT received successful hematopoietic cell transplantation (HCT: blood cell transplant from bone marrow) or gene therapy

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revcovi.

REFERENCES

Revcovi [Prescribing Information]. Cary, NJ: Chiesi USA, Inc.; August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 02/19
Client Approval: 06/24
P&T Approval: 01/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELBASVIR/GRAZOPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELBASVIR/ GRAZOPREVIR	ZEPATIER	43030		GPI-10 (1235990230)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older OR weighs at least 30 kg (66 lbs)
- The patient has genotype 1 or 4 infection

If yes, continue to #2.
If no, continue to #11.

2. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
- The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C)
- Zepatier will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., phenytoin, carbamazepine, rifampin, efavirenz [e.g., Atripla, Sustiva], atazanavir [e.g., Evotaz, Reyataz], darunavir [e.g., Prezcobix, Prezista], lopinavir, saquinavir, Aptivus [tipranavir], cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir [e.g., Stribild, Genvoya], atorvastatin at doses greater than 20mg daily, rosuvastatin at doses greater than 10mg daily, St. John's wort)
- Zepatier will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment-naïve **AND** meets the following criterion?
   - The patient had an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Harvoni, Mavyret

   If yes, continue to #5.
   If no, continue to #7.

5. Does the patient meet **ONE** of the following criteria?
   - The patient has genotype 1a infection AND does not have baseline NS5A polymorphisms
   - The patient has genotype 1b infection
   - The patient has genotype 4 infection
   - The patient is post-kidney transplant AND does not have baseline NS5A RAS polymorphisms

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

6. Does the patient meet **ALL** of the following criteria?
   - The patient has genotype 1a infection
   - The patient has baseline NS5A polymorphisms
   - Zepatier will be used with ribavirin

   If yes, **approve for 16 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #11.

7. Is the patient treatment-experienced **AND** meets the following criterion?
   - The patient had an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Harvoni, Mavyret

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

8. Does the patient have genotype 1 infection and meet **ONE** of the following criteria?
   - The patient has genotype 1a infection, without baseline NS5A polymorphisms, AND failed prior treatment with peginterferon/ribavirin
   - The patient has genotype 1b infection AND failed prior treatment with peginterferon/ribavirin
   - The patient failed prior treatment with a peginterferon/ribavirin/protease inhibitor triple regimen AND Zepatier will be used with ribavirin

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #9.

9. Does the patient meet **ONE** of the following criteria?
   - The patient has genotype 1a infection with baseline NS5A polymorphisms, failed prior treatment with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
   - The patient has genotype 4 infection, failed prior treatment with peginterferon/ribavirin, AND Zepatier will be used with ribavirin

   If yes, **approve for 16 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #10.

10. Is the patient post-kidney transplant and meets **ALL** of the following criteria?
    - The patient failed prior treatment with a non-direct acting antiviral agent (e.g., interferon)
    - The patient does not have baseline NS5A RAS polymorphisms

    If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
    If no, continue to #11.

11. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 12 years of age or older OR weigh at least 30 kilograms (66 pounds)
C. You have genotype 1 or 4 hepatitis C infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
G. You will NOT use Zepatier concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as phenytoin, carbamazepine, rifampin, efavirenz [such as Atripla, Sustiva], atazanavir [such as Evotaz, Reyataz], darunavir [such as Prezcobix, Prezista], lopinavir, saquinavir, Aptivus [tipranavir], cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir [such as Stribild, Genvoya], atorvastatin at doses greater than 20mg daily, rosuvastatin at doses greater than 10mg daily, St. John's wort)
H. You will NOT use Zepatier concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Mavyret (glecaprevir/pibrentasvir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
I. You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa, Harvoni, Mavyret
J. If you are treatment-naive (no prior treatment), approval also requires ONE of the following:
    1. You have genotype 1a infection AND you do not have baseline NS5A polymorphisms (variations in a type of hepatitis C virus protein)
    2. You have genotype 1b infection
    3. You have genotype 4 infection
    4. You received a kidney transplant (replaced your kidney) AND you do not have baseline NS5A resistance-associated substitution (RAS) polymorphisms (variations in a type of hepatitis C virus protein)
    5. You have genotype 1a infection, with baseline NS5A polymorphisms, AND Zepatier will be used with ribavirin

(Denial text continued on next page)

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ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

K. If you are treatment-experienced (failed prior treatment), approval also requires ONE of the following:
1. You have genotype 1a infection, without baseline NS5A polymorphisms (variations in a type of hepatitis C virus protein), AND were previously treated with peginterferon/ribavirin
2. You have genotype 1b infection AND were previously treated with peginterferon/ribavirin
3. You have genotype 1 infection, were previously treated with a peginterferon/ribavirin/protease inhibitor triple regimen, AND Zepatier will be used with ribavirin
4. You have genotype 1a infection with baseline NS5A polymorphisms, were previously treated with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
5. You have genotype 4 infection, were previously treated with peginterferon/ribavirin, AND Zepatier will be used with ribavirin
6. You received a kidney transplant (replaced your kidney), were previously treated with a non-direct acting antiviral (such as interferon), AND you do not have baseline NS5A resistance-associated substitution (RAS) polymorphisms (variations in a type of hepatitis C virus protein)

L. Zepatier will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zepatier.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 29, 2023.

Zepatier [Prescribing Information]. Rahway, NJ: Merck Sharl & Dohme LLC; March 2026.

Created: 02/16
Effective: 09/01/26 DMC Approval: 08/18/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELEXACAFTOR-TEZACAFTOR-IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR	TRIKAFTA	46112		GPI-10 (4530990340)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Trikafta will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient has at least ONE variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is either responsive to Trikafta based on clinical or in vitro data or that results in the production of CFTR protein

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   - **80-40-60mg granule packets: #2 per day.**
   - **100-50-75mg granule packets: #2 per day.**
   - **50-25-37.5mg tablets: #3 per day.**
   - **100-50-75mg tablets: #3 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (Trikafta)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
   D. You will NOT use Trikafta concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   E. You have at least ONE variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (a type of gene) that is either responsive to Trikafta based on clinical or in vitro data (testing outside of the body in a tube) or that results in the production of CFTR protein

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELEXACAFTOR-TEZACAFTOR-IVACAFTOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Trikafta will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by GPID or GPI-14 for all of the following:**
   - **80-40-60mg granule packets: #2 per day.**
   - **100-50-75mg granule packets: #2 per day.**
   - **50-25-37.5mg tablets: #3 per day.**
   - **100-50-75mg tablets: #3 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ELEXACAFTOR-TEZACAFTOR-IVACAFTOR (Trikafta)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Trikafta concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trikafta.

REFERENCES

Trikafta [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; March 2026.

Created: 02/20
Effective: 05/09/26 Client Approval: 05/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELINZANETANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELINZANETANT	LYNKUET	50837		GPI-10 (3060631500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) (ICD-10 N95.1) and meet **ALL** of the following criteria?
   - The patient experiences at least 7 hot flashes per day
   - Lynkuet will NOT be used concurrently with another hormonal (e.g., Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (e.g., Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) agent for VMS
   - The patient had a trial of or contraindication to the clinical standard of care agent: hormonal therapy (e.g., estradiol transdermal patch [e.g., Minivelle, Climara], oral conjugated estrogens [e.g., Premarin], micronized progesterone [e.g., Prometrium])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELINZANETANT (Lynkuet)** requires the following rule(s) be met for approval:
   A. You have moderate to severe menopausal vasomotor symptoms (VMS: symptoms related to menopause)
   B. You experience at least 7 hot flashes per day
   C. You will NOT use Lynkuet concurrently (at the same time) with another hormonal (such as Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (such as Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) medication for vasomotor symptoms (symptoms related to menopause)
   D. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: hormonal therapy (such as estradiol transdermal patch [such as Minivelle, Climara], oral conjugated estrogens [such as Premarin], micronized progesterone [such as Prometrium])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELINZANETANT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe menopausal vasomotor symptoms (VMS) (ICD-10 N95.1) and meet **ALL** of the following criteria?
   - The patient has a continued need for VMS treatment (persistently symptomatic with hot flashes)
   - The patient has had a reduction in VMS frequency or severity due to Lynkuet treatment
   - Lynkuet will NOT be used concurrently with another hormonal (e.g., Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (e.g., Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) agent for VMS

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELINZANETANT (Lynkuet)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe menopausal vasomotor symptoms (VMS: symptoms related to menopause)
   B. You have a continued need for vasomotor symptoms (symptoms related to menopause) treatment (persistently symptomatic with hot flashes)
   C. You have had a reduction in vasomotor symptoms (symptoms related to menopause) frequency or severity due to Lynkuet treatment
   D. You will NOT use Lynkuet concurrently (at the same time) with another hormonal (such as Prempro [conjugated estrogen/medroxyprogesterone]) or non-hormonal (such as Veozah [fezolinetant], Brisdelle [paroxetine mesylate]) medication for vasomotor symptoms (symptoms related to menopause)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lynkuet.

REFERENCES

Lynkuet [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2025.

Created: 11/25
Effective: 12/01/25 Client Approval: 11/25 P&T Approval: 04/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELOSULFASE ALFA (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELOSULFASE ALFA	VIMIZIM	40929		GPI-10 (3090703005)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)?

   If yes, **approve for lifetime by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELOSULFASE ALFA (Vimizim)** requires you have Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome - rare metabolic condition that mainly affects the skeleton).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vimizim.

REFERENCES

Vimizim [Prescribing Information]. Novato, CA: Biomarin Pharmaceutical Inc; December 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/14
Client Approval: 04/20
P&T Approval: 05/14

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELOTUZUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELOTUZUMAB	EMPLICITI	42842		GPI-10 (2135903000)	

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of multiple myeloma and meet **ONE** of the following criteria?
   - Empliciti (elotuzumab) will be used in combination with lenalidomide and dexamethasone in patients who have received one to three prior therapies for the treatment of multiple myeloma such as bortezomib, thalidomide, lenalidomide, melphalan, or stem cell transplantation
   - Empliciti (elotuzumab) will be used in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELOTUZUMAB (Empliciti)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (plasma cell cancer)
   B. You are 18 years of age or older
   C. You meet ONE of the following criteria:
      1. Empliciti is used in combination with lenalidomide and dexamethasone if you have received one to three prior therapies such as bortezomib, thalidomide, lenalidomide, melphalan, or stem cell transplantation
      2. Empliciti is used in combination with pomalidomide and dexamethasone if you have received at least two prior therapies including lenalidomide and a proteasome inhibitor (such as bortezomib, carfilzomib, ixazomib)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ELOTUZUMAB (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Empliciti.

REFERENCES

Empliciti [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; October 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 12/15
Client Approval: 03/21
P&T Approval: 02/16

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELRANATAMAB-BCMM (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELRANATAMAB-BCMM	ELREXFIO	49146		GPI-10 (2135202815)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least four prior lines of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab])

   If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 1 month for all strengths with the following quantity limits:**
     - **44 mg vial: #1.1 mL per 2 days for 2 fills.**
     - **76 mg vial: #5.7 mL per 21 days.**
   - **SECOND APPROVAL: Approve for 5 months with the following quantity limit (please enter a start date of 3 DAYS BEFORE the END date of the first approval):**
     - **76 mg vial: #7.6 mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELRANATAMAB-BCMM (Elrexfio)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have received at least four prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (such as Darzalex [daratumumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELRANATAMAB-BCMM (NSA)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma and meet **ALL** of the following criteria?
   - The patient has received at least 24 weeks of treatment with Elrexfio
   - The patient has responded to treatment with Elrexfio (a partial response [PR] or better), and has maintained this response for at least 2 months

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limit:**
   - **76 mg vial: #3.8 mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELRANATAMAB-BCMM (Elrexfio)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
   B. You have received at least 24 weeks of treatment with Elrexfio
   C. You have responded to treatment with Elrexfio (a partial response [PR] or better), and have maintained this response for at least 2 months

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elrexfio.

REFERENCES

Elrexfio [Prescribing Information]. New York, NY: Pfizer Inc.; August 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG - ALVAIZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELTROMBOPAG CHOLINE	ALVAIZ	49330		GPI-10 (8240503005)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial of or contraindication to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy
   - Alvaiz will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a platelet count of less than 30 x 10^9/L
   - The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **9mg: #1 per day.**
   - **18mg: #1 per day.**
   - **36mg: #2 per day.**
   - **54mg: #1 per day.**

   If no, continue to #4.

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ELTROMBOPAG - ALVAIZ

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of severe aplastic anemia (ICD-10 D61.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an insufficient response to immunosuppressive therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **18mg: #1 per day.**
   - **36mg: #2 per day.**
   - **54mg: #2 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - ALVAIZ** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
      2. Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C (a type of liver infection)
      3. Severe aplastic anemia (a type of blood disorder)

   B. If you have persistent or chronic immune (idiopathic) thrombocytopenia, approval also requires:
      1. You are 6 years of age or older
      2. You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, OR you did not have a good enough response to a splenectomy (spleen removal)
      3. You will NOT use Alvaiz concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim])
      4. You meet ONE of the following:
         a. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
         b. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L AND a prior bleeding event

   (Initial denial text continued on next page)

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ELTROMBOPAG - ALVAIZ

INITIAL CRITERIA (CONTINUED)

C. If you have thrombocytopenia due to chronic hepatitis C, approval also requires:
1. You are 18 years of age or older
2. Your thrombocytopenia does not allow you to start interferon-based therapy (a type of medication to treat liver infection) or limits your ability to maintain interferon-based therapy

D. If you have severe aplastic anemia, approval also requires:
1. You are 18 years of age or older
2. You did not have a good enough response to immunosuppressive therapy (treatment that lowers the activity of the body's immune system)

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ELTROMBOPAG - ALVAIZ

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events
   - Alvaiz will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - ALVAIZ** requires the following rules be met for renewal:
   A. You have persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
   B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Alvaiz) OR a decrease in bleeding events
   C. You will NOT use Alvaiz concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Promacta [eltrombopag], Doptelet [avatrombopag], Nplate [romiplostim])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alvaiz.

REFERENCES

Alvaiz [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; July 2024.

Created: 02/24
Effective: 08/01/26 DMC Approval: 07/21/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG - PROMACTA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELTROMBOPAG OLAMINE	PROMACTA	35989		GPI-10 (8240503010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: a corticosteroid or IV immunoglobulin, OR had an insufficient response to a splenectomy
   - Promacta will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a platelet count of less than 30 x 10^9/L
   - The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, **approve for 2 months by GPID or GPI-14 for all of the following strengths and formulations:**
   - **12.5mg tablet: #1 per day.**
   - **25mg tablet: #1 per day.**
   - **50mg tablet: #1 per day.**
   - **75mg tablet: #1 per day.**
   - **12.5mg packets: #1 per day.**
   - **25mg packets: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C **AND** meet the following criterion?
   - The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths and formulations:**
   - **12.5mg tablet: #1 per day.**
   - **25mg tablet: #1 per day.**
   - **50mg tablet: #2 per day.**
   - **75mg tablet: #1 per day.**
   - **12.5mg packets: #1 per day.**
   - **25mg packets: #4 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of severe aplastic anemia (ICD-10 D61.9)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the patient 2 years of age or older **AND** meets the following criterion?
   - Promacta will be used in combination with standard immunosuppressive therapy as first-line treatment

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths and formulations:**
   - **12.5mg tablet: #3 per day.**
   - **25mg tablet: #1 per day.**
   - **50mg tablet: #2 per day.**
   - **75mg tablet: #2 per day.**
   - **12.5mg packets: #3 per day.**
   - **25mg packets: #6 per day.**

   If no, continue to #6.

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ELTROMBOPAG - PROMACTA

INITIAL CRITERIA (CONTINUED)

6. Has the patient had an insufficient response to immunosuppressive therapy?

If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths and formulations:**

- **12.5mg tablet: #1 per day.**
- **25mg tablet: #1 per day.**
- **50mg tablet: #2 per day.**
- **75mg tablet: #2 per day.**
- **12.5mg packets: #1 per day.**
- **25mg packets: #6 per day.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELTROMBOPAG - PROMACTA** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Persistent or chronic immune (idiopathic) thrombocytopenia (a type of blood disorder)
   2. Thrombocytopenia (a type of blood disorder) due to chronic hepatitis C (a type of liver infection)
   3. Severe aplastic anemia (a type of blood disorder)

B. If you have persistent or chronic immune (idiopathic) thrombocytopenia, approval also requires:
   1. You are 1 year of age or older
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a corticosteroid or intravenous (injection into the vein) immunoglobulin, OR you did not have a good enough response to a splenectomy (spleen removal)
   3. You will NOT use Promacta concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag])
   4. You meet ONE of the following:
      a. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
      b. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L AND a prior bleeding event

(Initial denial text continued on next page)

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ELTROMBOPAG - PROMACTA

INITIAL CRITERIA (CONTINUED)

C. If you have thrombocytopenia due to chronic hepatitis C, approval also requires:
1. Your thrombocytopenia does not allow you to start interferon-based therapy (a type of medication to treat liver infection) or limits your ability to maintain interferon-based therapy

D. If you have severe aplastic anemia, approval also requires:
1. You meet ONE of the following:
   a. You are 2 years of age or older AND Promacta will be used in combination (together) with standard immunosuppressive therapy (treatment that lowers the activity of the body's immune system) as first-line treatment (used for initial treatment)
   b. You did not have a good enough response to immunosuppressive therapy (treatment that lowers the activity of the body's immune system)

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ELTROMBOPAG - PROMACTA

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of persistent or chronic immune (idiopathic) thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events
   - Promacta will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag])

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths and formulations:**
   - **12.5mg tablet: #1 per day.**
   - **25mg tablet: #1 per day.**
   - **50mg tablet: #1 per day.**
   - **75mg tablet: #1 per day.**
   - **12.5mg packets: #1 per day.**
   - **25mg packets: #3 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ELTROMBOPAG - PROMACTA** requires the following rules be met for renewal:
   A. You have persistent or chronic immune (idiopathic) thrombocytopenia (ITP: a type of blood disorder)
   B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Promacta) OR a decrease in bleeding events
   C. You will NOT use Promacta concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Nplate [romiplostim], Alvaiz [eltrombopag])

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ELTROMBOPAG - PROMACTA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Promacta.

REFERENCES

Promacta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2025.

Created: 01/09
Effective: 07/22/26 Client Approval: 07/26 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EMAPALUMAB-LZSG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EMAPALUMAB-LZSG	GAMIFANT	45503		GPI-10 (9940503540)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary (familial) hemophagocytic lymphohistiocytosis (HLH) (ICD-10 D76.1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an immunologist, hematologist, or oncologist
   - Gamifant will be used concurrently with dexamethasone
   - The patient has refractory, recurrent, or progressive disease OR the patient had a trial of or intolerance to conventional HLH therapy (chemotherapy, steroids, immunotherapy)

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's primary HLH diagnosis confirmed by **ONE** of the following criteria?
   - The patient has undergone a genetic test identifying HLH-associated gene mutation (e.g., PRF1, UNC13D)
   - The patient has at least five of the following eight diagnostic criteria for HLH: fever; splenomegaly; cytopenias (affecting at least 2 of 3 cell lineages); hypertriglyceridemia and/or hypofibrinogenemia; hemophagocytosis in bone marrow or spleen or lymph nodes, and no evidence of malignancy; low or absent natural killer-cell activity; ferritin level of at least 500 mcg/L; soluble CD25 level of at least 2,400 U/mL

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) (ICD-10 D76.1) and meet **ALL** of the following criteria?
   - The patient has known or suspected Still's disease or systemic juvenile idiopathic arthritis (sJIA)
   - The patient had an inadequate response or intolerance to glucocorticoids OR has a recurrent MAS

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EMAPALUMAB-LZSG

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EMAPALUMAB-LZSG (Gamifant)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary (familial) hemophagocytic lymphohistiocytosis (HLH: a type of genetic immune disorder)
   2. Hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) (a type of immune disorder)

B. If you have primary hemophagocytic lymphohistiocytosis, approval also requires:
   1. Therapy is prescribed by or in consultation with an immunologist (doctor who specializes in immune disorders), hematologist (a type of blood doctor), or oncologist (a type of cancer doctor)
   2. Gamifant will be used at the same time with dexamethasone
   3. You have refractory, recurrent, or progressive disease (disease does not respond to treatment, returns, or is getting worse) OR you have tried or had an intolerance (side effect) to conventional hemophagocytic lymphohistiocytosis therapy (chemotherapy, steroids, immunotherapy)
   4. Your diagnosis is confirmed by ONE of the following:
      a. You have undergone a genetic test identifying HLH-associated gene mutation (such as PRF1 [type of gene], UNC13D [type of gene])
      b. You have at least five of the following eight diagnostic criteria for HLH: fever; splenomegaly (enlarged spleen); cytopenias (low number of a type of blood cell affecting at least 2 of 3 cell lineages); hypertriglyceridemia (high level of triglycerides, a type of fat in blood) and/or hypofibrinogenemia (low level of fibrinogen, a type of protein in the blood); hemophagocytosis (destruction of certain types of cells) in bone marrow or spleen or lymph nodes, and no evidence of malignancy (cancer); low or absent natural killer-cell (white blood cells) activity; ferritin level (a type of lab test) of at least 500 mcg/L; soluble CD25 level (a type of lab test) of at least 2,400 U/mL

C. If you have hemophagocytic lymphohistiocytosis/macrophage activation syndrome, approval also requires:
   1. You have known or suspected Still's disease (an autoinflammatory disease) or systemic juvenile idiopathic arthritis (sJIA: a type of joint condition)
   2. You had an inadequate response (treatment did not work) or intolerance (side effect) to glucocorticoids OR you have a recurrent (disease has returned) macrophage activation syndrome (MAS: a type of immune disorder)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EMAPALUMAB-LZSG

RENEWAL CRITERIA

NOTE: For the diagnosis of hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of primary (familial) hemophagocytic lymphohistiocytosis (HLH) (ICD-10 D76.1) and meet **ALL** of the following criteria?
   - The patient has not received a successful hematopoietic stem cell transplantation
   - The patient has demonstrated improved immune system response from baseline as manifested by any of the following: resolution of fever, decreased splenomegaly, improvement in CNS symptoms (e.g., altered mental status), improved CBC, increased fibrinogen levels, reduced D- dimer, reduced ferritin, reduced soluble CD25 levels

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMAPALUMAB-LZSG (Gamifant)** requires the following rule(s) be met for renewal:
   A. You have primary (familial) hemophagocytic lymphohistiocytosis (HLH: a type of genetic immune disorder)
   B. You have not received a successful hematopoietic stem cell transplantation (bone marrow transplant)
   C. You have demonstrated improved immune system response from baseline as shown by any of the following: your fever has gone away, decreased splenomegaly (spleen size has gotten smaller), improvement in central nervous system symptoms (such as altered mental status), improved complete blood count, increased fibrinogen levels, or reduced D-dimer, ferritin, or soluble CD25 (types of proteins) levels

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Gamifant.

REFERENCES

Gamifant [Prescribing Information]. Waltham, MA: Sobi Inc.; June 2025.

Created: 03/19
Effective: 08/11/25 Client Approval: 07/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EMICIZUMAB-KXWH

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EMICIZUMAB-KXWH	HEMLIBRA	44640		GPI-10 (8510503020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist
   - Hemlibra will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   - Hemlibra will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hympavzi [marstacimab-hncq])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a patient WITH factor VIII inhibitors **AND** the patient meets the following criterion?
   - The patient has a history of a high titer of factor VIII inhibitor, defined as at least 5 Bethesda units per milliliter

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the request for a patient WITHOUT factor VIII inhibitors?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have moderate to severe hemophilia A, defined as less than 5 percent factor VIII activity compared to normal?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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EMICIZUMAB-KXWH

INITIAL CRITERIA (CONTINUED)

5. Does the patient have mild hemophilia A, defined as 5 percent - 40 percent factor VIII activity compared to normal, and meet **ONE** of the following criteria?
   - The patient has experienced severe, traumatic, or spontaneous bleeding episode(s) (may occur in joint or muscle)
   - The patient has experienced a life-threatening bleed (e.g., intracranial hemorrhage [ICH])
   - The patient has venous access difficulties impeding regular clotting factor infusions

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for approval:
   A. You have hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   C. Hemlibra will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   D. You will NOT use Hemlibra concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hympavzi [marstacimab-hncq])
   E. If you have hemophilia A with factor VIII inhibitors (a type of protein), approval also requires:
      1. You have a history of a high titer (concentration) of factor VIII inhibitor, defined as at least 5 Bethesda units per milliliter
   F. If you have hemophilia A without factor VIII inhibitors (a type of protein), approval also requires ONE of the following:
      1. You have moderate to severe hemophilia A, defined as less than 5 percent factor VIII activity compared to normal
      2. You have mild hemophilia A, defined as 5 percent - 40 percent factor VIII activity compared to normal, and meet ONE of the following:
         a. You have experienced severe, traumatic, or spontaneous (sudden) bleeding episode(s) (may occur in joint or muscle)
         b. You have experienced a life-threatening bleed (such as intracranial hemorrhage [ICH: a type of bleeding in the head])
         c. It is difficult to access your veins which prevents or delays you in receiving regular clotting factor infusions

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EMICIZUMAB-KXWH

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline
   - Hemlibra will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hympavzi [marstacimab-hncq])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for renewal:
   A. You have hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   B. You have shown a clinical benefit compared to baseline (before starting Hemlibra)
   C. You will NOT use Hemlibra concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hympavzi [marstacimab-hncq])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hemlibra.

REFERENCES

Hemlibra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; January 2024.

Created: 02/18
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENALAPRIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENALAPRIL MALEATE	EPANED, ENALAPRIL MALEATE	00130		GPI-10 (3610002010)	DOSAGE FORM = SOLUTION

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow enalapril tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of symptomatic heart failure (ICD-10 Group I50) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow enalapril tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of asymptomatic left ventricular dysfunction (ICD-10 I50.1, I51.9) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow enalapril tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ENALAPRIL

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENALAPRIL (Epaned)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hypertension (high blood pressure)
   2. Symptomatic heart failure (a type of heart condition)
   3. Asymptomatic left ventricular dysfunction (a type of heart condition)

B. If you have hypertension, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow enalapril tablets

C. If you have symptomatic heart failure, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow enalapril tablets

D. If you have asymptomatic left ventricular dysfunction, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow enalapril tablets

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Epaned.

REFERENCES

Epaned [Prescribing Information]. Wilmington, MA: Azurity Pharmaceuticals; July 2020.

Created: 07/25
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENASIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENASIDENIB MESYLATE	IDHIFA	44450		GPI-10 (2153503020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) (ICD-10 C92.02, C92.00) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA-approved diagnostic test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENASIDENIB (Idhifa)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: a type of blood and bone marrow cancer that has returned after or is resistant to treatment)
   B. You are 18 years of age or older
   C. You are isocitrate dehydrogenase-2 (a type of enzyme) mutation positive as detected by an FDA (Food and Drug Administration)-approved diagnostic test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Idhifa.

REFERENCES

Idhifa [Prescribing Information]. Summit, NJ: Celgene Corporation; December 2024.

Created: 08/17
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 10/17

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENCORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENCORAFENIB	BRAFTOVI	45039		GPI-10 (2153204000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation, as detected by an FDA-approved test
   - Braftovi will be used in combination with Mektovi (binimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a BRAF V600E mutation, as detected by an FDA-approved test
   - Braftovi will be used in combination with Erbitux (cetuximab) and fluorouracil-based chemotherapy (e.g., mFOLFOX6, FOLFIRI), OR Braftovi will be used in combination with Erbitux (cetuximab) and the patient has received prior therapy (e.g., irinotecan)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a BRAF V600E mutation, as detected by an FDA-approved test
   - Braftovi will be used in combination with Mektovi (binimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ENCORAFENIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENCORAFENIB (Braftovi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
   2. Metastatic colorectal cancer (mCRC: a type of digestive cancer that has spread to other parts of the body)
   3. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

B. If you have unresectable or metastatic melanoma, approval also requires:
   1. You have a BRAF V600E or V600K mutation (abnormal change in types of genes), as detected by a Food and Drug Administration (FDA)-approved test
   2. Braftovi will be used in combination with Mektovi (binimetinib)

C. If you have metastatic colorectal cancer, approval also requires:
   1. You are 18 years of age or older
   2. You have a BRAF V600E mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   3. You meet ONE of the following:
      a. Braftovi will be used in combination with Erbitux (cetuximab) and fluorouracil-based chemotherapy (such as mFOLFOX6 [fluorouracil, leucovorin and oxaliplatin], FOLFIRI [fluorouracil, leucovorin, and irinotecan])
      b. Braftovi will be used in combination with Erbitux (cetuximab), and you have previously received treatment (such as irinotecan)

D. If you have metastatic non-small cell lung cancer, approval also requires:
   1. You are 18 years of age or older
   2. You have a BRAF V600E mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   3. Braftovi will be used in combination with Mektovi (binimetinib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Braftovi.

REFERENCES

Braftovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc.; February 2026.

Created: 08/18
Effective: 03/11/26 Client Approval: 03/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENFORTUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENFORTUMAB VEDOTIN-EJFV	PADCEV	46257		GPI-10 (2135702620)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial cancer (mUC) (ICD-10 Groups C65, C66, C67, C68) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Will Padcev be used as a single agent and the patient meets **ONE** of the following criteria?
   - The patient has previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum (e.g., cisplatin, carboplatin)-containing chemotherapy
   - The patient is ineligible for cisplatin-containing chemotherapy AND has previously received one or more prior lines of therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Will Padcev be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of bladder cancer (ICD-10 Group C67) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has muscle invasive bladder cancer (MIBC)
   - Padcev will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph) as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ENFORTUMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENFORTUMAB (Padcev)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic urothelial cancer (mUC: type of urinary system cancer that has spread to nearby tissue or lymph nodes or to other parts of the body)
   2. Bladder cancer

B. If you have locally advanced or metastatic urothelial cancer, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Padcev will be used as a single agent, and you meet ONE of the following:
         i. You have previously received a medication that works against a type of protein called programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1), AND you have previously received a platinum (such as cisplatin, carboplatin)-containing chemotherapy (type of cancer medication)
         ii. You are not eligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy
      b. Padcev will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph)

C. If you have bladder cancer, approval also requires
   1. You are 18 years of age or older
   2. You have muscle invasive bladder cancer (MIBC: bladder cancer that has grown into the muscle wall)
   3. Padcev will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph), as neoadjuvant treatment (given before main treatment), and then continued after cystectomy (bladder removal surgery) as adjuvant treatment (additional treatment)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Padcev.

REFERENCES

Padcev [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc., July 2026.

Created: 02/20
Effective: 07/29/26 Client Approval: 07/26 DMC Approval: 07/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENSARTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENSARTINIB HYDROCHLORIDE	ENSACOVE	50112		GPI-10 (2153301520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive
   - The patient has NOT previously received an ALK-inhibitor (e.g., Xalkori [crizotinib], Alecensa [alectinib])

   If yes, **approve all strengths for 12 months by GPID or GPI-14 as follows:**
   - **25mg: #9 per day.**
   - **100mg: #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENSARTINIB (Ensacove)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue/lymph nodes or other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive
   D. You have NOT previously received an ALK-inhibitor (such as Xalkori [crizotinib], Alecensa [alectinib])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ensacove.

REFERENCES

Ensacove [Prescribing Information]. Miami, FL: Xcovery Holdings, Inc.; December 2024.

Created: 06/25
Effective: 07/01/25 Client Approval: 06/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENSIFENTRINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENSIFENTRINE	OHTUVAYRE	49726		GPI-10 (4443002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ohtuvayre will be used as maintenance treatment
   - Therapy is prescribed by or in consultation with a pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a blood eosinophil level of 100 cells/microliter or greater?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   - LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist)/ICS (inhaled corticosteroid) combination drug (e.g., Trelegy Ellipta, Breztri Aerosphere)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #5mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   - LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (e.g., Stiolto Respimat, Anoro Ellipta)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #5mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ENSIFENTRINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENSIFENTRINE (Ohtuvayre)** requires the following rule(s) be met for approval:

A. You have chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
B. You are 18 years of age or older
C. Ohtuvayre will be used as maintenance treatment (taken on a regular basis)
D. Therapy is prescribed by or in consultation with a pulmonologist (a type of lung/breathing doctor)
E. You have a history of and will continue on, or you had a contraindication (harmful for you to use) or failure (drug did not work) to ONE of the following standard of care therapies:
    1. LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (such as Stiolto Respimat, Anoro Ellipta)
    2. LAMA/LABA/ICS (inhaled corticosteroid) combination drug (such as Trelegy Ellipta, Breztri Aerosphere) if you have a blood eosinophil level of 100 cells/microliter or greater

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENSIFENTRINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and ICD-10 J44.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have a blood eosinophil level of 100 cells/microliter or greater?

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   - LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist)/ICS (inhaled corticosteroid) combination drug (e.g., Trelegy Ellipta, Breztri Aerosphere)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient had a history of and will continue on, or has a contraindication or failure to, the following standard of care therapy?
   - LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (e.g., Stiolto Respimat, Anoro Ellipta)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - The patient has a reduction in COPD exacerbations from baseline
   - The patient has a reduction in severity or frequency of COPD-related symptoms (e.g., wheezing, shortness of breath, coughing, sputum production, etc.)
   - The patient has an increase in FEV1 by at least 5 percent from pretreatment baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ENSIFENTRINE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENSIFENTRINE (Ohtuvayre)** requires the following rule(s) be met for renewal:

A. You have chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
B. You have a history of and will continue on, or you had a contraindication (harmful for you to use) or failure (drug did not work) to ONE of the following standard of care therapies:
    1. LAMA (long-acting antimuscarinic)/LABA (long-acting beta-2-agonist) combination drug (such as Stiolto Respimat, Anoro Ellipta)
    2. LAMA/LABA/ICS (inhaled corticosteroid) combination drug (such as Trelegy Ellipta, Breztri Aerosphere) if you have a blood eosinophil level of 100 cells/microliter or greater
C. You have shown a clinical response as evidenced by ONE of the following:
    1. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Ohtuvayre)
    2. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum (mucus) production, etc.)
    3. You have an increase in FEV1 (a type of lung test) by at least 5 percent from pretreatment baseline (before starting Ohtuvayre)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ohtuvayre.

REFERENCES

Ohtuvayre [Prescribing Information]. Raleigh, NC: Verona Pharma, Inc.; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 07/24
Client Approval: 07/24
P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENTRECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENTRECTINIB	ROZLYTREK	45952		GPI-10 (2153382000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is *ROS1*-positive as detected by an FDA-approved test

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of a solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, as detected by an FDA-approved test
   - The tumor is metastatic or surgical resection is likely to result in severe morbidity
   - The patient has progressed following treatment or there are no satisfactory alternative treatments

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Rozlytrek (100 mg or 200 mg) capsules?

   If yes, **approve both 100 mg and 200 mg capsules for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100 mg: #5 per day.**
   - **200 mg: #3 per day.**

   If no, continue to #4.

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ENTRECTINIB

GUIDELINES FOR USE (CONTINUED)

4. Is the request for Rozlytrek 50 mg pellets and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to Rozlytrek capsules made into an oral suspension
   - The patient has difficulty or is unable to swallow capsules

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **50 mg: #12 per day.**
   - **100 mg: #5 per day.**
   - **200 mg: #3 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ENTRECTINIB (Rozlytrek)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
      2. Solid tumor (an abnormal mass)

   B. If you have metastatic non-small cell lung cancer, approval also requires:
      1. You are 18 years of age or older
      2. Your tumor is ROS1-positive (abnormal change in a type of gene) as detected by a Food and Drug Administration (FDA)-approved test

   C. If you have a solid tumor, approval also requires:
      1. You are 1 month of age or older
      2. The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation (an abnormal change in a type of gene that does not have any known resistance), as detected by a Food and Drug Administration (FDA)-approved test
      3. Your tumor is metastatic (has spread to other parts of the body), or surgical resection (removal) is likely to result in severe morbidity (disease)
      4. You have progressed (gotten worse) after treatment or there are no satisfactory alternative treatments

   (Denial text continues on the next page)

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ENTRECTINIB

GUIDELINES FOR USE (CONTINUED)

D. If the request is for Rozlytrek 50 mg pellets, approval also requires:

1. You have tried or have a contraindication to (harmful for you to use) Rozlytrek capsules that are used to make an oral suspension
2. You have difficulty or are not able to swallow capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rozlytrek.

REFERENCES

Rozlytrek [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; January 2024.

Created: 11/19
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ENZALUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ENZALUTAMIDE	XTANDI	39580		GPI-10 (2140243000)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Castration-resistant prostate cancer (CRPC) (ICD-10 Z19.2, C61)
   - Metastatic castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61)

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC) (ICD-10 Z19.1, C61) **AND** meet the following criterion?
   - The patient is at high risk for metastasis (i.e., prostate specific antigen [PSA] doubling time over 9 months or less)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has received a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Xtandi will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **40 mg: #4 per day.**
   - **80 mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ENZALUTAMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ENZALUTAMIDE (Xtandi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Castration-resistant prostate cancer (CRPC: prostate cancer that does not respond to hormone therapy)
   2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
   3. Non-metastatic castration-sensitive prostate cancer (nmCSPC: prostate cancer that has not spread to other parts of the body and responds to hormone therapy)

B. If you have castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer, approval also requires ONE of the following:
   1. You have received a bilateral orchiectomy (surgical removal of both testicles)
   2. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
   3. Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

C. If you have non-metastatic castration-sensitive prostate cancer, approval also requires:
   1. You are at high risk for metastasis (prostate specific antigen [PSA] level has doubled over 9 months or less)
   2. You meet ONE of the following:
      a. You have received a bilateral orchiectomy (surgical removal of both testicles)
      b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      c. Xtandi will be used concurrently (at the same time) with a gonadotropin releasing hormone analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ENZALUTAMIDE

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Xtandi.

REFERENCES

Xtandi [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; March 2025.

Created: 09/12
Effective: 11/10/25 Client Approval: 10/25 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPCORITAMAB-BYSP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPCORITAMAB-BYSP	EPKINLY	48945		GPI-10 (2135203120)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3) (including DLBCL arising from indolent lymphoma) or high-grade B-cell lymphoma, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient previously received at least two lines of systemic therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (FL) (ICD-10 Group C82) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - Epkinly will be used in combination with lenalidomide (Revlimid) and rituximab
   - Epkinly will be used as monotherapy after receiving at least two lines of systemic therapy (e.g., Gazyva [obinutuzumab], bendamustine, rituximab, Revlimid [lenalidomide])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPCORITAMAB-BYSP (Epkinly)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: a type of blood cancer that has returned or is not responding to treatment), including DLBCL arising from indolent (slow growing) lymphoma (a type of blood cancer), OR high-grade B-cell lymphoma (a type of blood cancer)
      2. Relapsed or refractory follicular lymphoma (FL: a type of blood cancer that has returned or is not responding to treatment)

   (Denial text continued on next page)

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EPCORITAMAB-BYSP

GUIDELINES FOR USE (CONTINUED)

B. If you have diffuse large B-cell lymphoma or high-grade B-cell lymphoma, approval also requires:
1. You are 18 years of age or older
2. You previously received at least two lines of systemic therapy (treatment that travels throughout the body) (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])

C. If you have follicular lymphoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Epkinly will be used in combination with lenalidomide (Revlimid) and rituximab
   b. Epkinly will be used as monotherapy (one medication treatment) after receiving at least two lines of systemic therapy (treatment that travels throughout the body) (such as Gazyva [obinutuzumab], bendamustine, rituximab, Revlimid [lenalidomide])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Epkinly.

REFERENCES
Epkinly [Prescribing Information]. Plainsboro, NJ: Genmab US, Inc.; November 2025.

Created: 07/23
Effective: 12/15/25 Client Approval: 12/25 P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPLONTERSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPLONTERSEN SODIUM	WAINUA	49355		GPI-10 (6270102510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   - The patient is ambulatory (i.e., Familial Amyloid Polyneuropathy [FAP] stage 1 - 2 or Polyneuropathy Disability [PND] Stage I - IIIb polyneuropathy)
   - Wainua will NOT be used concurrently with other hATTR-PN agents (e.g. Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the hATTR diagnosis confirmed by **ONE** of the following?
   - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
   - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.8mL per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EPLONTERSEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPLONTERSEN (Wainua)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
D. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
E. You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])
F. Your diagnosis is confirmed by ONE of the following:
    1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
    2. DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPLONTERSEN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient has not progressed to Familial Amyloid Polyneuropathy (FAP) stage 3 or Polyneuropathy Disability (PND) Stage IV polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   - Wainua will NOT be used concurrently with other hATTR-PN agents (e.g. Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.8mL per 30 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPLONTERSEN (Wainua)** requires the following rule(s) be met for renewal:
   A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
   B. You have not progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 or Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage IV polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
   C. You will NOT use Wainua concurrently (at the same time) with other hATTR-PN medications (such as Tegsedi [inotersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPLONTERSEN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wainua.

REFERENCES

Wainua [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/24
Client Approval: 05/24
P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOETIN ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPOETIN ALFA	EPOGEN, PROCRIT	04553		GPI-10 (8240102000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL
   - The requested medication will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #2.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 11g/dL OR the patient's hemoglobin level has decreased at least 2g/dL below baseline level
   - The requested medication will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #3.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy and meet **ALL** of the following criteria?
- The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
- The patient's hemoglobin level is less than 10g/dL
- The requested medication will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
- **Procrit 2,000U/mL: #12mL per 28 days.**
- **Procrit 3,000U/mL: #12mL per 28 days.**
- **Procrit 4,000U/mL: #12mL per 28 days.**
- **Procrit 10,000U/mL: #12mL per 28 days.**
- **Procrit 20,000U/mL: #12mL per 28 days.**
- **Procrit 40,000U/mL: #4mL per 28 days.**
- **Procrit 20,000U/2mL: #12mL per 28 days.**
- **Epogen 2,000U/mL: #12mL per 28 days.**
- **Epogen 3,000U/mL: #12mL per 28 days.**
- **Epogen 4,000U/mL: #12mL per 28 days.**
- **Epogen 10,000U/mL: #12mL per 28 days.**
- **Epogen 20,000U/mL: #12mL per 28 days.**
- **Epogen 20,000U/2mL: #12mL per 28 days.**

If no, continue to #4.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL
   - The patient had a trial of or contraindication to ribavirin dose reduction
   - The requested medication will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #5.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

5. Is the patient undergoing elective, noncardiac, nonvascular surgery and meets **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 13g/dL
   - The requested medication will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 1 month by GPID or GPI-14 for the requested strength as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
   2. Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
   3. Anemia (a type of blood condition) related to zidovudine (Retrovir) therapy (a type of medication to treat human immunodeficiency virus [HIV: an immune system disease caused by a virus])
   4. Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart or blood vessels)

B. If you have anemia due to chronic kidney disease, approval also requires:
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level (a type of blood test) is less than 10g/dL
   3. You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia- inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

C. If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:
   1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
   2. Your hemoglobin level (a type of blood test) is less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level
   3. You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia- inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

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EPOETIN ALFA

INITIAL CRITERIA (CONTINUED)

D. If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:
1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
2. Your hemoglobin level (a type of blood test) is less than 10g/dL
3. You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia- inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

E. If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
2. Your hemoglobin level (a type of blood test) is less than 10g/dL
3. You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
4. You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia- inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

F. If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:
1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
2. Your hemoglobin level (a type of blood test) is less than 13g/dL
3. You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia- inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPOETIN ALFA

RENEWAL CRITERIA

NOTE: Requests for patients undergoing elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL if not on dialysis
   - The patient's hemoglobin level is less than 11g/dL if on dialysis
   - The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions
   - The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #3.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

3. Is the request for a pediatric patient (less than 18 years of age) and the patient meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient's hemoglobin level has approached or exceeds 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL
   - The requested medication will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, continue to #5.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy and meet **ALL** of the following criteria?
- The patient's hemoglobin level is between 10g/dL and 12g/dL
- The requested medication will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
- **Procrit 2,000U/mL: #12mL per 28 days.**
- **Procrit 3,000U/mL: #12mL per 28 days.**
- **Procrit 4,000U/mL: #12mL per 28 days.**
- **Procrit 10,000U/mL: #12mL per 28 days.**
- **Procrit 20,000U/mL: #12mL per 28 days.**
- **Procrit 40,000U/mL: #4mL per 28 days.**
- **Procrit 20,000U/2mL: #12mL per 28 days.**
- **Epogen 2,000U/mL: #12mL per 28 days.**
- **Epogen 3,000U/mL: #12mL per 28 days.**
- **Epogen 4,000U/mL: #12mL per 28 days.**
- **Epogen 10,000U/mL: #12mL per 28 days.**
- **Epogen 20,000U/mL: #12mL per 28 days.**
- **Epogen 20,000U/2mL: #12mL per 28 days.**

If no, continue to #6.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL
   - The requested medication will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows**:
   - **Procrit 2,000U/mL: #12mL per 28 days.**
   - **Procrit 3,000U/mL: #12mL per 28 days.**
   - **Procrit 4,000U/mL: #12mL per 28 days.**
   - **Procrit 10,000U/mL: #12mL per 28 days.**
   - **Procrit 20,000U/mL: #12mL per 28 days.**
   - **Procrit 40,000U/mL: #4mL per 28 days.**
   - **Procrit 20,000U/2mL: #12mL per 28 days.**
   - **Epogen 2,000U/mL: #12mL per 28 days.**
   - **Epogen 3,000U/mL: #12mL per 28 days.**
   - **Epogen 4,000U/mL: #12mL per 28 days.**
   - **Epogen 10,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/mL: #12mL per 28 days.**
   - **Epogen 20,000U/2mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPOETIN ALFA (Procrit, Epogen)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
   2. Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
   3. Anemia (a type of blood condition) related to zidovudine (Retrovir) therapy (a type of medication to treat human immunodeficiency virus [HIV: an immune system disease caused by a virus])
   4. Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. If you have anemia due to chronic kidney disease, renewal also requires:
   1. You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia- inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])
   2. If you are an adult (you are 18 years of age or older), renewal also requires ONE of the following:
      a. Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
      b. Your hemoglobin level (a type of blood test) is less than 11g/dL if you are on dialysis (process of removing excess water, toxins from the blood)
      c. Your hemoglobin level (a type of blood test) has reached 10g/dL (if you are not on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
      d. Your hemoglobin level (a type of blood test) has reached 11g/dL (if you are on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
   3. If you are a pediatric patient (you are less than 18 years of age), renewal also requires ONE of the following:
      a. Your hemoglobin level (a type of blood test) is less than 10g/dL
      b. Your hemoglobin level (a type of blood test) has approached or exceeds 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

(Renewal denial text continued on next page)

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EPOETIN ALFA

RENEWAL CRITERIA (CONTINUED)

C. If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
1. Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
2. You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia- inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

D. If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:
1. Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
2. You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia- inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

E. If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
1. Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
2. You will NOT use the requested medication concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta) OR hypoxia- inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Procrit, Epogen.

REFERENCES

Procrit [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2024.
Epogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2024.

Created: 02/11
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOETIN ALFA-EPBX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPOETIN ALFA-EPBX	RETACRIT	44931		GPI-10 (8240102004)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - Retacrit will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, continue to #2.

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is less than 11g/dL OR the patient's hemoglobin level has decreased at least 2g/dL below baseline level
   - Retacrit will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - Retacrit will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, continue to #4.

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient had a trial of or contraindication to ribavirin dose reduction
   - Retacrit will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, continue to #5.

5. Is the patient undergoing elective, noncardiac, nonvascular surgery and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is less than 13g/dL
   - Retacrit will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 1 month by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
   2. Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
   3. Anemia (a type of blood condition) related to zidovudine (Retrovir) therapy (a type of medication to treat human immunodeficiency virus [HIV: an immune system disease caused by a virus])
   4. Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac, nonvascular surgery (surgery not relating to the heart or blood vessels)

B. If you have anemia due to chronic kidney disease, approval also requires:
   1. Your hemoglobin level (a type of blood test) is less than 10g/dL
   2. You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

C. If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:
   1. Your hemoglobin level (a type of blood test) is less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level
   2. You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

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EPOETIN ALFA-EPBX

INITIAL CRITERIA (CONTINUED)

D. If you have anemia related to zidovudine (Retrovir) therapy, approval also requires:
1. Your hemoglobin level (a type of blood test) is less than 10g/dL
2. You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

E. If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
1. Your hemoglobin level (a type of blood test) is less than 10g/dL
2. You have tried or have a contraindication to (harmful for you to use) a lower ribavirin dose
3. You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

F. If you are undergoing elective, noncardiac, nonvascular surgery, approval also requires:
1. Your hemoglobin level (a type of blood test) is less than 13g/dL
2. You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA

NOTE: Requests for patients undergoing elective, noncardiac, nonvascular surgery, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   - Retacrit will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient an adult (18 years of age or older) and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL if not on dialysis
   - The patient's hemoglobin level is less than 11g/dL if on dialysis
   - The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions
   - The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, continue to #3.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

3. Is the request for a pediatric patient (less than 18 years of age) and the patient meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL
   - The patient's hemoglobin level has approached or exceeds 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy (ICD-10 D64.81) and meet **ALL** of the following criteria?
   - The patient's hemoglobin level is between 10g/dL and 12g/dL
   - Retacrit will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **2,000U/mL: #12mL per 28 days.**
   - **3,000U/mL: #12mL per 28 days.**
   - **4,000U/mL: #12mL per 28 days.**
   - **10,000U/mL: #12mL per 28 days.**
   - **20,000U/mL: #12mL per 28 days.**
   - **40,000U/mL: #4mL per 28 days.**
   - **20,000U/2mL: #12mL per 28 days.**

   If no, continue to #5.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of anemia related to zidovudine (Retrovir) therapy and meet **ALL** of the following criteria?
- The patient's hemoglobin level is between 10g/dL and 12g/dL
- Retacrit will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
- **2,000U/mL: #12mL per 28 days.**
- **3,000U/mL: #12mL per 28 days.**
- **4,000U/mL: #12mL per 28 days.**
- **10,000U/mL: #12mL per 28 days.**
- **20,000U/mL: #12mL per 28 days.**
- **40,000U/mL: #4mL per 28 days.**
- **20,000U/2mL: #12mL per 28 days.**

If no, continue to #6.

6. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?
- The patient's hemoglobin level is between 10g/dL and 12g/dL
- Retacrit will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF- PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

If yes, **approve for 6 months by GPID or GPI-14 for the requested strength as follows:**
- **2,000U/mL: #12mL per 28 days.**
- **3,000U/mL: #12mL per 28 days.**
- **4,000U/mL: #12mL per 28 days.**
- **10,000U/mL: #12mL per 28 days.**
- **20,000U/mL: #12mL per 28 days.**
- **40,000U/mL: #4mL per 28 days.**
- **20,000U/2mL: #12mL per 28 days.**

If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPOETIN ALFA-EPBX (Retacrit)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
   2. Anemia (a type of blood condition) due to the effect of concomitantly administered (given at the same time) cancer chemotherapy (medications used to treat cancer)
   3. Anemia (a type of blood condition) related to zidovudine (Retrovir) therapy (a type of medication to treat human immunodeficiency virus [HIV: an immune system disease caused by a virus])
   4. Anemia (a type of blood condition) due to hepatitis C (a type of liver infection) combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. If you have anemia due to chronic kidney disease, renewal also requires:
   1. You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])
   2. If you are an adult (you are 18 years of age or older), renewal also requires ONE of the following:
      a. Your hemoglobin level (a type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
      b. Your hemoglobin level (a type of blood test) is less than 11g/dL if you are on dialysis (process of removing excess water, toxins from the blood)
      c. Your hemoglobin level (a type of blood test) has reached 10g/dL (if you are not on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
      d. Your hemoglobin level (a type of blood test) has reached 11g/dL (if you are on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
   3. If you are a pediatric patient (you are less than 18 years of age), renewal also requires ONE of the following:
      a. Your hemoglobin level (a type of blood test) is less than 10g/dL
      b. Your hemoglobin level (a type of blood test) has approached or exceeds 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

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EPOETIN ALFA-EPBX

RENEWAL CRITERIA (CONTINUED)

C. If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
1. Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
2. You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

D. If you have anemia related to zidovudine (Retrovir) therapy, renewal also requires:
1. Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
2. You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

E. If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
1. Your hemoglobin level (a type of blood test) is between 10g/dL and 12g/dL
2. You will NOT use Retacrit concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Retacrit.

REFERENCES
Retacrit [Prescribing Information]. Lake Forest, IL: Pfizer Inc.; June 2024.

Created: 02/11
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOPROSTENOL IV (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPOPROSTENOL SODIUM (GLYCINE)	FLOLAN, EPOPROSTENOL SODIUM	07323		GPI-10 (4017004010)	
EPOPROSTENOL SODIUM	VELETRI, EPOPROSTENOL SODIUM	37762			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EPOPROSTENOL IV (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPOPROSTENOL IV (Flolan, Veletri)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPOPROSTENOL IV (NSA)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes**, approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPOPROSTENOL IV (Flolan, Veletri)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Flolan and Veletri.

REFERENCES

Flolan [Prescribing Information]. Durham, NC: GlaxoSmithKline; October 2023.
Veletri [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; July 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 09/05
Client Approval: 06/24
P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EPTINEZUMAB-JJMR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EPTINEZUMAB-JJMR	VYEPTI	46372		GPI-10 (6770201520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Vyepti is prescribed for the preventive treatment of migraines
   - Vyepti will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   - The patient had a trial of TWO of the following preferred agents: Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm), Nurtec ODT (rimegepant), Qulipta (atogepant), Ajovy (fremanezumab-vfrm)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines (ICD-10 Group G43.7, G43.E) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Vyepti is prescribed for the preventive treatment of migraines
   - Vyepti will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention
   - The patient had a trial of TWO of the following preferred agents: Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm), Nurtec ODT (rimegepant), Qulipta (atogepant), Ajovy (fremanezumab-vfrm)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EPTINEZUMAB-JJMR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Episodic migraines (a type of headache)
   2. Chronic migraines (a type of headache)

B. If you have episodic migraines (0-14 headache days per month), approval also requires:
   1. You are 18 years of age or older
   2. Vyepti is prescribed for the preventive treatment of migraines (a type of headache)
   3. You will NOT use Vyepti concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention
   4. You have tried TWO of the following preferred medications: Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm), Nurtec ODT (rimegepant), Qulipta (atogepant), Ajovy (fremanezumab-vfrm)

C. If you have chronic migraines (at least 15 headache days per month), approval also requires:
   1. You are 18 years of age or older
   2. Vyepti is prescribed for the preventive treatment of migraines (a type of headache)
   3. You will NOT use Vyepti concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention
   4. You have tried TWO of the following preferred medications: Aimovig (erenumab-aooe), Emgality (galcanezumab-gnlm), Nurtec ODT (rimegepant), Qulipta (atogepant), Ajovy (fremanezumab-vfrm)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPTINEZUMAB-JJMR

RENEWAL CRITERIA

1. Is the request for the preventive treatment of migraines **AND** the patient meets the following criterion?
   - Vyepti will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Vyepti therapy
   - The patient has experienced a reduction in migraine severity with Vyepti therapy
   - The patient has experienced a reduction in migraine duration with Vyepti therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for renewal:
   A. The request is for the preventive treatment of migraines (a type of headache)
   B. You will NOT use Vyepti concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention
   C. You meet ONE of the following:
      1. You have experienced a decrease in migraine (a type of headache) or headache frequency of at least 2 days per month with Vyepti therapy
      2. You have experienced a decrease in migraine (a type of headache) severity with Vyepti therapy
      3. You have experienced a decrease in migraine (a type of headache) duration with Vyepti therapy

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EPTINEZUMAB-JJMR

RATIONALE

For further information, please refer to the Prescribing information and/or Drug Monograph for Vyepti.

REFERENCES

Vyepti [Prescribing Information]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; October 2025.

Created: 03/20
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERDAFITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERDAFITINIB	BALVERSA	45687		GPI-10 (2153222500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (i.e., bladder cancer) (ICD-10 Groups C65, C66, C67, C68) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible FGFR3 genetic alteration as detected by an FDA-approved companion diagnostic test
   - The patient has disease progression on or after at least one line of prior systemic therapy (e.g., cisplatin, Keytruda [pembrolizumab])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **3mg: #3 per day.**
   - **4mg: #2 per day.**
   - **5mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERDAFITINIB (Balversa)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic urothelial carcinoma (a type of bladder cancer that has spread to nearby tissue or other parts of the body)
   B. You are 18 years of age or older
   C. You have a susceptible (can be treated with the drug) fibroblast growth factor receptor 3 (FGFR3: a type of protein) genetic alteration (mutation) as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
   D. You have disease progression (condition has worsened) on or after at least one line of prior systemic therapy (treatment that targets the entire body, such as cisplatin, Keytruda [pembrolizumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERDAFITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Balversa.

REFERENCES

Balversa [Prescribing Information]. Horsham, PA: Janssen Products, LP; October 2024.

Created: 04/19
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERENUMAB-AOOE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERENUMAB-AOOE	AIMOVIG	44923		GPI-10 (6770202010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Aimovig is prescribed for the preventive treatment of migraines
   - Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines (ICD-10 Groups G43.7, G43.E) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Aimovig is prescribed for the preventive treatment of migraines
   - Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ERENUMAB-AOOE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Episodic migraines (a type of headache)
   2. Chronic migraines (a type of headache)

B. If you have episodic migraines (0-14 headache days per month), approval also requires:
   1. You are 18 years of age or older
   2. Aimovig is prescribed for the preventive treatment of migraines (a type of headache)
   3. You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention

C. If you have chronic migraines (15 or more headache days per month), approval also requires:
   1. You are 18 years of age or older
   2. Aimovig is prescribed for the preventive treatment of migraines (a type of headache)
   3. You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERENUMAB-AOOE

RENEWAL CRITERIA

1. Is the request for the preventive treatment of migraines **AND** the patient meets the following criterion?
   - Aimovig will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Aimovig therapy
   - The patient has experienced a reduction in migraine severity with Aimovig therapy
   - The patient has experienced a reduction in migraine duration with Aimovig therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:
   A. The request is for the preventive treatment of migraines (a type of headache)
   B. You will NOT use Aimovig concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention
   C. You meet ONE of the following:
      1. You have experienced a decrease in migraine (a type of headache) or headache frequency of at least 2 days per month with Aimovig therapy
      2. You have experienced a decrease in migraine (a type of headache) severity with Aimovig therapy
      3. You have experienced a decrease in migraine (a type of headache) duration with Aimovig therapy

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ERENUMAB-AOOE

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Aimovig.

REFERENCE
Aimovig [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; March 2025.

Created: 05/18
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERGOTAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERGOTAMINE TARTRATE	ERGOMAR	01869		GPI-10 (6700002010)	BRAND = ERGOMAR

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ergomar will NOT be used concurrently with any other dihydroergotamine or ergotamine product (e.g., Migranal [dihydroergotamine], Migergot [ergotamine-caffeine])

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient had a trial of or contraindication to **ALL** of the following preferred agents?
   - Two triptans (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan], Relpax [eletriptan])
   - One generic dihydroergotamine product (e.g., dihydroergotamine mesylate 1mg/mL, dihydroergotamine mesylate 0.5mg/spry)
   - One CGRP inhibitor: Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for the treatment of cluster headache (ICD-10 Groups G44.00, G44.01, G44.02) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's symptoms were NOT adequately managed with abortive therapies (e.g., Imitrex [sumatriptan], Zomig [zolmitriptan], oxygen)
   - Ergomar will NOT be used concurrently with any additional dihydroergotamine or ergotamine product (e.g., Migranal [dihydroergotamine], Migergot [ergotamine-caffeine])
   - The patient had a trial of or contraindication to the clinical standard of care agent for preventive treatment: verapamil

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ERGOTAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERGOTAMINE (Ergomar)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Acute (quick onset) treatment of migraines (a type of headache)
   2. Treatment of cluster headache (a type of headache)

B. If the request is for the acute treatment of migraines, approval also requires:
   1. You are 18 years of age or older
   2. You will NOT use Ergomar concurrently (at the same time) with any other dihydroergotamine or ergotamine medication (such as Migranal [dihydroergotamine], Migergot [ergotamine-caffeine])
   3. You have tried or have a contraindication to (harmful for you to use) ALL of the following preferred medications:
      a. Two triptans (such as Imitrex [sumatriptan], Maxalt [rizatriptan], Relpax [eletriptan])
      b. One generic dihydroergotamine product (such as dihydroergotamine mesylate 1mg/mL, dihydroergotamine mesylate 0.5mg/spry)
      c. One calcitonin gene-related peptide (CGRP) inhibitor: Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)

C. If the request is for the treatment of cluster headache, approval also requires:
   1. You are 18 years of age or older
   2. Your symptoms were NOT adequately managed with abortive therapies (such as Imitrex [sumatriptan], Zomig [zolmitriptan], oxygen)
   3. You will NOT use Ergomar concurrently (at the same time) with any additional dihydroergotamine or ergotamine medication (such as Migranal [dihydroergotamine], Migergot [ergotamine-caffeine])
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication for preventive treatment: verapamil

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ERGOTAMINE

RENEWAL CRITERIA

NOTE: For the request for the acute treatment of migraines, please refer to the Initial Criteria section.

1. Is the request for the treatment of cluster headache (ICD-10 Groups G44.00, G44.01, G44.02) and the patient meets **ALL** of the following criteria?
   - The patient had improvement in cluster headache frequency as compared to baseline
   - Ergomar will NOT be used concurrently with any additional dihydroergotamine or ergotamine product (e.g., Migranal [dihydroergotamine], Migergot [ergotamine-caffeine])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERGOTAMINE (Ergomar)** requires the following rule(s) be met for renewal:
   A. The request is for the treatment of cluster headache (a type of headache)
   B. You had improvement in cluster headache frequency as compared to baseline (before treatment)
   C. You will NOT use Ergomar concurrently (at the same time) with any additional dihydroergotamine or ergotamine medication (such as Migranal [dihydroergotamine], Migergot [ergotamine-caffeine])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ergomar.

REFERENCES

Ergomar [Prescribing Information]. Brielle, NJ: Pangea Pharmaceuticals, LLC; February 2025.

Created: 05/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 01/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERIBULIN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERIBULIN MESYLATE	HALAVEN, ERIBULIN MESYLATE	37256		GPI-10 (2150000920)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer **AND** meet the following criterion?
   - The patient has tried at least TWO chemotherapeutic regimens in the adjuvant or metastatic setting, which include one agent from EACH of the following drug classes:
     - An anthracycline (e.g., daunorubicin [Cerubidine], doxorubicin [Adriamycin], epirubicin [Ellence])
     - A taxane (e.g., docetaxel [Taxotere], paclitaxel [Taxol, Abraxane])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable or metastatic liposarcoma **AND** meet the following criterion?
   - The patient has tried an anthracycline-containing regimen (e.g., daunorubicin [Cerubidine], doxorubicin [Adriamycin], epirubicin [Ellence])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ERIBULIN (Halaven)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Metastatic breast cancer (cancer that has spread to other parts of the body)
      2. Unresectable or metastatic liposarcoma (cancer that begins in the fat cells and cannot be completely removed with surgery or that has spread to other parts of the body)

   B. If you have metastatic breast cancer, approval also requires:
      1. You have tried at least TWO chemotherapeutic regimens (drugs used to treat cancer) in the adjuvant (add on treatment) or metastatic setting, which include one medication from EACH of the following drug classes:
         a. An anthracycline (a type of cancer treatment such as daunorubicin [Cerubidine], doxorubicin [Adriamycin], epirubicin [Ellence])
         b. A taxane (a type of cancer treatment such as docetaxel [Taxotere], paclitaxel [Taxol, Abraxane])

   (Denial text continued on next page)

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ERIBULIN (NSA)

GUIDELINES FOR USE (CONTINUED)

C. If you have unresectable or metastatic liposarcoma, approval also requires:

1. You have tried an anthracycline-containing regimen (a type of cancer treatment such as daunorubicin [Cerubidine], doxorubicin [Adriamycin], epirubicin [Ellence])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Halaven.

REFERENCES

Halaven [Prescribing Information]. Nutley, NJ: Eisai Inc.; April 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: NA
Commercial Effective: 05/06/24
Created: 11/10
Client Approval: 04/24
P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ERLOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ERLOTINIB HCL	TARCEVA, ERLOTINIB HCL	26745		GPI-10 (2136002510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
   - Tarceva (erlotinib) will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Gilotrif [afatinib], Tagrisso [osimertinib], Iressa [gefitinib], Vizimpro [dacomitinib])

   If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
   - **25mg: #2 per day.**
   - **100mg: #2 per day.**
   - **150mg: #3 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer (ICD-10 C25) **AND** meet the following criterion?
   - The requested medication will be used in combination with gemcitabine

   If yes, **approve for 12 months by GPID or GPI-14 as requested with the following quantity limits:**
   - **25mg: #2 per day.**
   - **100mg: #2 per day.**
   - **150mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ERLOTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ERLOTINIB (Tarceva)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
   2. Locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread or cannot be completely removed by surgery)

B. If you have metastatic non-small cell lung cancer, approval also requires:
   1. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of gene mutations or permanent change in the DNA that make up a gene) as detected by an FDA (Food and Drug Administration)- approved test
   2. You will NOT use Tarceva (erlotinib) concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (such as Gilotrif [afatinib], Tagrisso [osimertinib], Iressa [gefitinib], Vizimpro [dacomitinib])

C. If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:
   1. The requested medication will be used in combination with gemcitabine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tarceva.

REFERENCES

Tarceva [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; October 2016.

Created: 11/10
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ESKETAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ESKETAMINE HCL	SPRAVATO	41003		GPI-10 (5811002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of treatment-resistant depression (TRD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a psychiatrist or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider
   - The patient has non-psychotic, unipolar depression
   - The patient does NOT have active substance abuse

   (**NOTE:** Treatment resistant depression is defined as a treatment failure after trial of two or more antidepressant medications of adequate dose and duration.)

   If yes, **approve for a total of 6 months by HICL or GPI-10 as follows:**
   - **INDUCTION DOSE: Approve for 30 days with a quantity limit of #1 per day.**
   - **MAINTENANCE DOSE: Approve for 5 months with a quantity limit of #12 per 28 days (Enter a start date of 2 days before the end of the induction dose approval).**

   If no, continue to #2.

2. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Spravato will be used in combination with an oral antidepressant (e.g., Zoloft [sertraline], Cymbalta [duloxetine])
   - The patient has acute suicidal ideation or behavior
   - Therapy is prescribed by or in consultation with a psychiatrist or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider
   - The patient has non-psychotic, unipolar depression
   - The patient does NOT have active substance abuse

   If yes, **approve for 2 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ESKETAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Treatment-resistant depression (TRD: depressive symptoms are not responding to treatment)
   2. Major depressive disorder (MDD: a type of mental illness)

B. If you have treatment-resistant depression, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor) or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider (a doctor that is authorized to prescribe the requested medication)
   3. You have non-psychotic, unipolar depression (you have depression that does not involve hallucinations or delusions)
   4. You do NOT have active substance (drug) abuse

C. If you have major depressive disorder, approval also requires:
   1. You are 18 years of age or older
   2. Spravato will be used in combination with an oral antidepressant (such as Zoloft [sertraline], Cymbalta [duloxetine])
   3. You have acute (short-term) suicidal ideation or behavior (thoughts of killing yourself)
   4. Therapy is prescribed by or in consultation with a psychiatrist (a type of mental health doctor) or other Risk Evaluation and Mitigation Strategy (REMS)-certified provider (a doctor that is authorized to prescribe the requested medication)
   5. You have non-psychotic, unipolar depression (you have depression that does not involve hallucinations or delusions)
   6. You do NOT have active substance (drug) abuse

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ESKETAMINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of treatment-resistant depression (TRD) **AND** meet the following criterion?
   - The patient has demonstrated clinical benefit (improvement in depression) compared to baseline
     (**NOTE:** Treatment resistant depression is defined as a treatment failure after trial of two or more antidepressant medications of adequate dose and duration.)

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #12 per 28 days.**
     If no, continue to #2.

2. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) **AND** meet the following criterion?
   - The patient has demonstrated clinical benefit (improvement in depression) compared to baseline

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
     If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for renewal:
     A. You have ONE of the following:
        1. Treatment-resistant depression (TRD: depressive symptoms are not responding to treatment)
        2. Major depressive disorder (MDD: a type of mental illness)
     B. You have demonstrated clinical benefit (improvement in depression) compared to baseline (before treatment)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spravato.

REFERENCES

Spravato [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; April 2025.

Created: 05/19
Effective: 07/27/26 Client Approval: 07/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETANERCEPT	ENBREL	18830		GPI-10 (6629003000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 mL per 28 days.**
   If no, continue to #4.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., naproxen, ibuprofen, meloxicam)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4 mL per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 4 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant and PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

7. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Enbrel
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

   If yes, **approve for a total of 6 months by HICL or GPI-10. Please enter two approvals as follows:**
   - **FIRST APPROVAL: Approve for 3 months with a quantity limit of #8 mL per 28 days.**
   - **SECOND APPROVAL: Approve for 3 months with a quantity limit of #4 mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      3. Psoriatic arthritis (PsA: a type of skin and joint condition)
      4. Ankylosing spondylitis (AS: a type of joint condition)
      5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)

   B. If you have moderate to severe rheumatoid arthritis, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
      3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis
      4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   (Initial denial text continued on next page)

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

D. If you have psoriatic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

E. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as naproxen, ibuprofen, meloxicam)

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ETANERCEPT

INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe plaque psoriasis, approval also requires:

1. You are 4 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
4. You meet ONE of the following:
   a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
5. You meet ONE of the following:
   a. You were previously stable on another biologic and are switching to Enbrel
   b. You have psoriasis covering 3 percent or more of body surface area (BSA)
   c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETANERCEPT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
   If no, continue to #4.

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.** If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   - Enbrel will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETANERCEPT (Enbrel)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      3. Psoriatic arthritis (PsA: a type of skin and joint condition)
      4. Ankylosing spondylitis (AS: a type of joint condition)
      5. Moderate to severe plaque psoriasis (PsO: a type of skin condition)

   (Renewal denial text continued on next page)

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ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis

C. If you have moderate to severe polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis

D. If you have psoriatic arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

E. If you have ankylosing spondylitis, renewal also requires:
1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

F. If you have moderate to severe plaque psoriasis, renewal also requires:
1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
2. You will NOT use Enbrel concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETANERCEPT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enbrel.

REFERENCES

Enbrel [Prescribing Information]. Thousand Oaks, CA: Immunex Corporation; September 2024.

Created: 02/03
Effective: 06/24/26 Client Approval: 06/26 P&T Approval: 01/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETELCALCETIDE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETELCALCETIDE	PARSABIV	44093		GPI-10 (3090523010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of secondary hyperparathyroidism (HPT) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has chronic kidney disease
   - The patient is on hemodialysis
   - The patient is NOT taking another calcimimetic agent (e.g., cinacalcet)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #36mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETELCALCETIDE (Parsabiv)** requires the following rule(s) be met for approval:
   A. You have secondary hyperparathyroidism (too much parathyroid hormone due to low blood calcium levels)
   B. You are 18 years of age or older
   C. You have chronic kidney disease
   D. You are on hemodialysis (a way of removing toxins from your blood)
   E. You are NOT taking another calcimimetic agent (a drug that acts like calcium in the body
   F. such as cinacalcet)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETELCALCETIDE (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Parsabiv.

REFERENCES

Parsabiv [Prescribing Information]. Thousand Oaks, CA: Kai Pharmaceuticals; March 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 02/18
Client Approval: 04/20

P&T Approval: 01/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETEPLIRSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETEPLIRSEN	EXONDYS-51	43770		GPI-10 (7460003500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   - The patient has a confirmed mutation of the DMD gene that is amenable to exon 51 skipping therapy
   - Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of DMD at a DMD treatment center
   - The patient is ambulatory
   - The patient is currently receiving treatment with or has a contraindication to corticosteroids (e.g., prednisone, prednisolone)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETEPLIRSEN (Exondys 51)** requires the following rule(s) be met for approval:
   A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   B. You have a confirmed mutation (abnormal change in a type of gene) in the DMD gene that will respond to exon 51 skipping therapy (a type of therapy to treat DMD)
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) specializing in the treatment of DMD at a DMD treatment center
   D. You are ambulatory (able to walk)
   E. You are currently receiving treatment with or you have a contraindication to (harmful for you to use) corticosteroids (such as prednisone, prednisolone)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETEPLIRSEN

RENEWAL CRITERIA

1. Does the patient meet **ONE** of the following criteria?
   - The patient has maintained or demonstrated a less than expected decline in ambulatory ability based on muscle function assessments (e.g., 6-minute walk test)
   - The patient has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETEPLIRSEN (Exondys 51)** requires ONE of the following rule(s) be met for renewal:
   A. You have maintained or demonstrated a less than expected decline in ambulatory ability (ability to walk) based on muscle function assessments (such as the 6-minute walk test)
   B. You have maintained or demonstrated a less than expected decline in other muscle function (pulmonary [lung] or cardiac [heart] function)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exondys 51.

REFERENCES

Exondys 51 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc.; December 2024.

Created: 01/16
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETHACRYNIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETHACRYNIC ACID	EDECRIN, ETHACRYNIC ACID	03659		GPI-10 (3720002000)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Edema (ICD-10 Group R60) associated with congestive heart failure, cirrhosis of the liver, or renal disease (including nephrotic syndrome)
   - Ascites (ICD-10 Group R18) due to malignancy, idiopathic edema, or lymphedema

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **TWO** preferred generic loop diuretics (e.g., furosemide, bumetanide, torsemide)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ETHACRYNIC ACID (Edecrin)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), cirrhosis (liver damage), or renal disease (including nephrotic syndrome [a type of kidney disorder])
      2. Ascites (accumulation of fluid in the abdominal cavity) due to malignancy (cancer), idiopathic (unknown cause) edema, or lymphedema (swelling in an arm or leg due to build-up of lymph fluid)
   B. You have tried or have a contraindication to (harmful for you to use) TWO preferred generic loop diuretics (such as furosemide, bumetanide, torsemide)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ETHACRYNIC ACID

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Edecrin.

REFERENCES

Edecrin [Prescribing Information]. Greenville, NC: Bausch Health Companies, Inc., August 2020.

Created: 05/22
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ETRASIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ETRASIMOD ARGININE	VELSIPITY	49267		GPI-10 (5250452510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Velsipity will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ETRASIMOD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ETRASIMOD (Velsipity)** requires the following rule(s) be met for approval:

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
D. You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    2. Skyrizi (risankizumab-rzaa)
    3. Tremfya (guselkumab)
    4. Omvoh (mirikizumab-mrkz)
    5. Adalimumab-ryvk/adalimumab-aaty
    6. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
    7. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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ETRASIMOD

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Velsipity will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ETRASIMOD

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ETRASIMOD (Velsipity)** requires the following rule(s) be met for renewal:

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You will NOT use Velsipity concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    2. Skyrizi (risankizumab-rzaa)
    3. Tremfya (guselkumab)
    4. Omvoh (mirikizumab-mrkz)
    5. Adalimumab-ryvk/adalimumab-aaty
    6. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
    7. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Velsipity.

REFERENCES

Velsipity [Prescribing Information]. New York, NY: Pfizer, Inc.; August 2025.

Created: 10/23
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EVEROLIMUS-AFINITOR DISPERZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EVEROLIMUS	AFINITOR DISPERZ, EVEROLIMUS		34589 34590 34592	GPI-14 (21532530007310 21532530007320 21532530007340)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA) (ICD-10 Q85.1 and D43.2) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures (ICD-10 Q85.1 and Groups G40.1, G40.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The requested medication will be used as adjunctive treatment
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to ONE preferred agent: an antiepileptic medication (e.g., vigabatrin, carbamazepine, levetiracetam, oxcarbazepine, valproic acid derivatives, clobazam, topiramate, lamotrigine)
   - The patient had a trial of or contraindication to the preferred agent: Epidiolex (cannabidiol)

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EVEROLIMUS-AFINITOR DISPERZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **EVEROLIMUS-AFINITOR DISPERZ** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)
   2. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures (type of seizure)

B. If you have tuberous sclerosis complex-associated subependymal giant cell astrocytoma, approval also requires:
   1. You are 1 year of age or older
   2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely remove with surgery)

C. If you have tuberous sclerosis complex-associated partial-onset seizures, approval also requires:
   1. You are 2 years of age or older
   2. The requested medication will be used as adjunctive (add-on) treatment
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   4. You have tried or have a contraindication to (harmful for you to use) ONE preferred medication: an anti-seizure medication (such as vigabatrin, carbamazepine, levetiracetam, oxcarbazepine, valproic acid derivatives, clobazam, topiramate, lamotrigine)
   5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Epidiolex (cannabidiol)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EVEROLIMUS-AFINITOR DISPERZ

RENEWAL CRITERIA

NOTE: For the diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures (ICD-10 Q85.1 and Groups G40.1, G40.2)?

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EVEROLIMUS-AFINITOR DISPERZ** requires the following rule(s) be met for renewal:
   A. You have tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures (type of seizure)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afinitor Disperz.

REFERENCES

Afinitor/Afinitor Disperz [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. February 2022.

Created: 03/23
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EVEROLIMUS-AFINITOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EVEROLIMUS	AFINITOR, TORPENZ, YULITHIRA, EVEROLIMUS		20784 20844 28783 31396	GPI-14 (21532530000330 21532530000310 21532530000320 21532530000325)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
- The patient is a postmenopausal woman
- The patient's breast cancer is hormone receptor (HR)-positive, HER2-negative
- The requested medication will be used in combination with exemestane
- The patient has failed or has a contraindication to treatment with Femara (letrozole) or Arimidex (anastrozole)

If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
- **2.5mg: #1 per day.**
- **5mg: #1 per day.**
- **7.5mg: #2 per day.**
- **10mg: #2 per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of progressive neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease (ICD-10 Group C7A) **AND** meet the following criterion?
- The patient is 18 years of age or older

If yes, continue to #3.
If no, continue to #4.

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EVEROLIMUS-AFINITOR

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient has neuroendocrine tumors of pancreatic origin (PNET)
   - The patient has well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, continue to #5.

5. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated renal angiomyolipoma (ICD-10 Q85.1 and D17.71) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does NOT require immediate surgery

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
   - **2.5mg: #1 per day.**
   - **5mg: #1 per day.**
   - **7.5mg: #2 per day.**
   - **10mg: #2 per day.**

   If no, continue to #6.

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EVEROLIMUS-AFINITOR

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma (SEGA) (ICD-10 Q85.1 and D43.2) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, continue to #7.

7. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures (ICD-10 Q85.1 and Groups G40.1, G40.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The requested medication will be used as adjunctive treatment
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to ONE clinical standard of care agent: an antiepileptic medication (e.g., vigabatrin, carbamazepine, levetiracetam, oxcarbazepine, valproic acid derivatives, clobazam, topiramate, lamotrigine)
   - The patient had a trial of or contraindication to the clinical standard of care agent: Epidiolex (cannabidiol)

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EVEROLIMUS-AFINITOR (Afinitor, Torpenz, Yulithira)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Advanced breast cancer
      2. Progressive, neuroendocrine tumors (NET: a rare type of tumor) with unresectable (unable to remove by surgery), locally advanced (cancer that has spread to nearby tissue or lymph nodes) or metastatic disease (cancer that has spread to other parts of the body)
      3. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      4. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated renal angiomyolipoma (type of kidney tumor)
      5. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated subependymal giant cell astrocytoma (SEGA: a type of brain tumor)
      6. Tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures (type of seizure)

(Initial denial text continued on next page)

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EVEROLIMUS-AFINITOR

INITIAL CRITERIA (CONTINUED)

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EVEROLIMUS-AFINITOR

INITIAL CRITERIA (CONTINUED)

B. If you have advanced breast cancer, approval also requires:
1. You are a postmenopausal (after menopause) woman
2. Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
3. The requested medication will be used in combination with exemestane
4. You have failed or have a contraindication to (harmful for you to use) treatment with Femara (letrozole) or Arimidex (anastrozole)

C. If you have progressive neuroendocrine tumors with unresectable, locally advanced or metastatic disease, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have neuroendocrine tumors of pancreatic origin (PNET: tumor in the pancreas)
   b. You have well-differentiated, non-functional neuroendocrine tumors (NET: a rare type of tumor) of gastrointestinal (GI: relating to the digestive system) or lung origin

D. If you have advanced renal cell carcinoma, approval also requires:
1. You are 18 years of age or older

E. If you have tuberous sclerosis complex-associated renal angiomyolipoma, approval also requires:
1. You are 18 years of age or older
2. You do NOT require immediate surgery

F. If you have tuberous sclerosis complex-associated subependymal giant cell astrocytoma, approval also requires:
1. You are 1 year of age or older
2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely removed with surgery)

G. If you have tuberous sclerosis complex-associated partial-onset seizures, approval also requires:
1. You are 2 years of age or older
2. The requested medication will be used as adjunctive (add-on) treatment
3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
4. You have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: an anti-seizure medication (such as vigabatrin, carbamazepine, levetiracetam, oxcarbazepine, valproic acid derivatives, clobazam, topiramate, lamotrigine)
5. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: Epidiolex (cannabidiol)

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EVEROLIMUS-AFINITOR

RENEWAL CRITERIA

NOTE: For the diagnoses of advanced breast cancer, progressive neuroendocrine tumors with unresectable, locally advanced or metastatic disease, advanced renal cell carcinoma, tuberous sclerosis complex (TSC)-associated renal angiomyolipoma, and tuberous sclerosis complex (TSC)-associated subependymal giant cell astrocytoma, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of tuberous sclerosis complex (TSC)-associated partial-onset seizures (ICD-10 Q85.1 and Groups G40.1, G40.2)?

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EVEROLIMUS-AFINITOR (Afinitor, Torpenz, Yulithira)** requires the following rule(s) be met for renewal:
   A. You have tuberous sclerosis complex (TSC: a rare type of tumor disorder)-associated partial-onset seizures (type of seizure)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afinitor and Torpenz.

REFERENCES

Afinitor/Afinitor Disperz [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2022.
Torpenz [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; February 2026.

Created: 05/11
Effective: 05/16/26 Client Approval: 05/26 P&T Approval: 07/25

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EVINACUMAB-DGNB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EVINACUMAB-DGNB	EVKEEZA	47113		GPI-10 (3939203020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) (ICD-10 E78.01) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Evkeeza will be used as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies
   - Therapy is prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist
   - The patient had a trial of or contraindication to Zetia (ezetimibe)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   - Given that the patient cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), the patient is currently taking a maximally tolerated dose of any statin

   If yes, continue to #3.
   If no, continue to #4.

3. Will the patient continue statin treatment as described above in combination with Evkeeza?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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EVINACUMAB-DGNB

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has complete statin intolerance (defined by severe and intolerable adverse effects) (e.g., creatine kinase elevation at least 10 times the upper limit of normal, liver function test elevation at least 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least TWO separate statins AND have improved with the discontinuation of each statin

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agent: Repatha (evolocumab)
   - The patient lacks functioning low-density lipoprotein (LDL) receptors

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EVINACUMAB-DGNB (Evkeeza)** requires the following rule(s) be met for approval:
   A. You have homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
   B. You are 1 year of age or older
   C. Evkeeza will be used as an adjunct (add-on) to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies
   D. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), endocrinologist (a type of hormone doctor), or lipidologist (a type of cholesterol doctor)
   E. You have tried or have a contraindication to (harmful for you to use) Zetia (ezetimibe)
   F. You meet ONE of the following:
      1. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Repatha (evolocumab)
      2. You do NOT have functional LDL (low-density lipoprotein) receptors

(Initial denial text continued on the next page)

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EVINACUMAB-DGNB

INITIAL CRITERIA (CONTINUED)

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EVINACUMAB-DGNB

INITIAL CRITERIA (CONTINUED)

G. If you are statin tolerant, approval also requires:
1. You meet ONE of the following:
   a. You are currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   b. You did not tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), but you are currently taking a maximally tolerated dose of any statin
2. You will continue statin treatment in combination with Evkeeza

H. If you are statin intolerant, approval also requires ONE of the following:
1. You have an absolute contraindication to (harmful for you to use) statin therapy (such as active decompensated liver disease [symptoms related to liver damage], nursing [breastfeeding] female, pregnancy or plans to become pregnant, hypersensitivity [allergic] reaction)
2. You have complete statin intolerance (defined by severe and intolerable adverse effects) that have occurred with trials of at least TWO separate statins, AND the adverse effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation at least 10 times the upper limit of normal, liver function test elevation at least 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EVINACUMAB-DGNB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) (ICD-10 E78.01) **AND** meet the following criterion?
   - The patient's low-density lipoprotein-cholesterol (LDL-C) level has decreased while on Evkeeza

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has continued concurrent therapy with a maximally tolerated dose of ANY statin
   - The patient has an absolute contraindication to statin therapy
   - The patient has complete statin intolerance

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EVINACUMAB-DGNB (Evkeeza)** requires the following rule(s) be met for renewal:
   A. You have homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
   B. Your low-density lipoprotein-cholesterol (LDL-C) level has decreased while on Evkeeza
   C. You meet ONE of the following:
      1. You have continued to take a maximally tolerated dose of ANY statin along with Evkeeza
      2. You have an absolute contraindication to (harmful for you to use) statin therapy
      3. You have complete statin intolerance (severe and intolerable adverse effects)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evkeeza.

REFERENCES

Evkeeza [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2025.

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FAM-TRASTUZUMAB DERUXTECAN-NXKI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FAM-TRASTUZUMAB DERUXTECAN-NXKI	ENHERTU	46262		GPI-10 (2135507055)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50)?

   If yes, continue to #2.
   If no, continue to #8.

2. Is the patient's cancer unresectable or metastatic?

   If yes, continue to #3.
   If no, continue to #6.

3. Is the patient's cancer HER2-positive (IHC 3+ or ISH positive) and the patient meets **ONE** of the following criteria?
   - The patient has received a prior anti-HER2-based regimen (e.g., Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emtansine]) in the metastatic setting
   - The patient has received a prior anti-HER2-based regimen (e.g., Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emtansine]) in the neoadjuvant or adjuvant setting AND has developed disease recurrence during or within 6 months of completing therapy
   - Enhertu will be used in combination with pertuzumab (Perjeta), when cancer is determined by an FDA-authorized test

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient's cancer HR-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining), as determined by an FDA-authorized test, **AND** the patient meets the following criterion?
   - The patient's disease has progressed on at least one endocrine therapy (e.g., letrozole, anastrozole, tamoxifen) in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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FAM-TRASTUZUMAB DERUXTECAN-NXKI

GUIDELINES FOR USE (CONTINUED)

5. Is the patient's cancer HER2-low (IHC 1+ or IHC 2+/ISH-), as determined by an FDA-authorized test and the patient meets **ONE** of the following criteria?
   - The patient has received prior chemotherapy in the metastatic setting
   - The patient has developed disease recurrence during or within 6 months of completing adjuvant chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   Is the patient's cancer in early Stage II or III and meets **ALL** of the following criteria?
6. Is the patient's cancer in early stage and meets **ALL** of the following criteria?
   - The patient's cancer is HER2-positive (IHC3+ or ISH+)
   - Enhertu will be used as adjuvant treatment
   - The patient has residual invasive disease following neoadjuvant trastuzumab and taxane- based treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have unresectable or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors have activating HER2 (ERBB2) mutations, as determined by an FDA-authorized test
   - The patient has received a prior systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

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FAM-TRASTUZUMAB DERUXTECAN-NXKI

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have a diagnosis of locally advanced or metastatic gastric OR gastroesophageal junction (GEJ) adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is HER2-positive (IHC 3+ or IHC 2+/ISH positive)
   - The patient has received a prior trastuzumab-based regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #10.

9. Does the patient have a diagnosis of unresectable or metastatic solid tumors and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is HER2-positive (IHC 3+)
   - The patient has received prior systemic treatment and has no satisfactory alternative treatment options

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FAM-TRASTUZUMAB DERUXTECAN-NXKI (Enhertu)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Unresectable or metastatic breast cancer (a type of cancer that cannot be removed by surgery or has spread to other parts of the body)
      2. Early breast cancer
      3. Unresectable or metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that cannot be removed by surgery or has spread to other parts of the body)
      4. Locally advanced or metastatic gastric OR gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
      5. Unresectable or metastatic solid tumors (a type of abnormal mass that cannot be removed by surgery or has spread to other parts of the body)

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FAM-TRASTUZUMAB DERUXTECAN-NXKI

GUIDELINES FOR USE (CONTINUED)

B. If you have unresectable or metastatic breast cancer, approval also requires ONE of the following:

1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or ISH positive), and you meet ONE of the following:
   a. You have received a prior anti-HER2-based regimen (such as Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emtansine]) in the metastatic setting (cancer has spread to other parts of the body)
   b. You have received a prior anti-HER2-based regimen (such as Herceptin [trastuzumab], Kadcyla [ado-trastuzumab emtansine]) in the neoadjuvant (given before main treatment) or adjuvant (additional treatment) setting AND the disease returned during or within 6 months of completing therapy
   c. You will use Enhertu in combination with pertuzumab (Perjeta), when your cancer is determined by a Food and Drug Administration (FDA)-authorized test
2. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining), as determined by a Food and Drug Administration (FDA)-authorized test, AND your disease has progressed (worsened) while on at least one endocrine therapy (such as letrozole, anastrozole, tamoxifen) in the metastatic setting (cancer has spread to other parts of the body)
3. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-low (IHC 1+ or IHC 2+/ISH-), as determined by a Food and Drug Administration (FDA)-authorized test, and you meet ONE of the following:
   a. You have received a prior chemotherapy (a type of cancer treatment) in the metastatic setting (cancer has spread to other parts of the body)
   b. You have developed disease recurrence (disease has returned) during or within 6 months of completing adjuvant (additional) chemotherapy

C. If you have early breast cancer, approval also requires ONE of the following:

1. Your cancer is early Stage II or III; your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or ISH positive), as determined by a Food and Drug Administration (FDA)-authorized test; AND Enhertu will be used as a neoadjuvant treatment (given before main treatment) and followed by a taxane (such as paclitaxel), trastuzumab, and pertuzumab (THP)
2. Your cancer is in early stage; your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or ISH positive); Enhertu will be used as adjuvant treatment (additional treatment); and you have residual invasive disease (remaining disease that has spread) following neoadjuvant (given before main treatment) trastuzumab and taxane-based treatment

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FAM-TRASTUZUMAB DERUXTECAN-NXKI

GUIDELINES FOR USE (CONTINUED)

D. If you have unresectable or metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumors have activating HER2 (ERBB2) mutations (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-authorized test
3. You have received a prior systemic therapy (treatment that targets the entire body)

E. If you have locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or IHC 2+/ISH positive)
3. You have received a prior trastuzumab-based (type of medication) regimen

F. If you have unresectable or metastatic solid tumors, approval also requires:
1. You are 18 years of age or older
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+)
3. You have received previous systemic treatment (therapy that targets the entire body) and have no other satisfactory treatment options

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RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Enhertu.

REFERENCES
Enhertu [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; May 2026.

Created: 02/20
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FARICIMAB-SVOA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FARICIMAB-SVOA	VABYSMO	47786		GPI-10 (8665252270)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   Vabysmo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve for 4 months by HICL or GPI-10 for 4 fills with a quantity limit of #0.1mL per 21 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   Vabysmo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve for 6 months by HICL or GPI-10 for 6 fills with a quantity limit of #0.1mL per 21 days.**

   If no, continue to #3.

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FARICIMAB-SVOA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
   Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   Vabysmo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab])
   The patient had a trial of or contraindication to ONE of the following preferred agents: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

   If yes**, approve for 6 months by HICL or GPI-10 with a quantity limit of #0.1mL per 21 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FARICIMAB-SVOA (Vabysmo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
      2. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
      3. Macular edema following retinal vein occlusion (RVO: a type of eye condition)

   B. If you have neovascular (wet) age-related macular degeneration, approval also requires:
      1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
      2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

   C. If you have diabetic macular edema, approval also requires:
      1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
      2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

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FARICIMAB-SVOA

INITIAL CRITERIA (CONTINUED)

D. If you have macular edema following retinal vein occlusion, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Cimerli (ranibizumab-eqrn), Byooviz (ranibizumab-nuna)

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FARICIMAB-SVOA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   - The patient has maintained or improved visual acuity
   - Vabysmo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 56 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
   - The patient has maintained or improved visual acuity
   - Vabysmo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 56 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
   - The patient has maintained or improved visual acuity
   - Vabysmo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab])

   If yes**, approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 21 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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FARICIMAB-SVOA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FARICIMAB-SVOA (Vabysmo)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
   2. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
   3. Macular edema following retinal vein occlusion (RVO: a type of eye condition)

B. If you have neovascular (wet) age-related macular degeneration, renewal also requires:
   1. You have maintained or improved visual acuity (vison clarity or sharpness)
   2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

C. If you have diabetic macular edema, renewal also requires:
   1. You have maintained or improved visual acuity (vison clarity or sharpness)
   2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

D. If you have macular edema following retinal vein occlusion, renewal also requires:
   1. You have maintained or improved visual acuity (vison clarity or sharpness)
   2. You will NOT use Vabysmo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vabysmo.

REFERENCES

Vabysmo [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; April 2026.

Created: 05/22
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA CAPSULE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FECAL MICROBIO SPORE, LIVE-BRPK	VOWST	48888		GPI-10 (5252202010)	

GUIDELINES FOR USE

1. Is the request for the prevention of recurrent *Clostridioides difficile* infection (CDI) (ICD-10 A04.71) and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist or infectious disease specialist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received treatment with Vowst?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient completed antibiotic treatment (e.g., vancomycin [Vancocin], fidaxomicin [Dificid]) for the treatment of recurrent CDI (defined as at least 3 CDI episodes)?

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #12 per 3 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst, AND a positive stool test for *C. difficile*
   - The patient has NOT previously received more than 1 treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #12 per 3 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA CAPSULE

GUIDELINES FOR USE

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FECAL MICROBIOTA CAPSULE (Vowst)** requires the following rule(s) be met for approval:

A. Vowst will be used for the prevention of recurrent *Clostridioides difficile (C. difficile)* infection (CDI: a bacterial infection)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or infectious disease specialist (a doctor who specializes in the treatment of infections)
D. If you have NOT previously been treated with Vowst, approval also requires:
   1. You have completed antibiotic (such as vancomycin [Vancocin], fidaxomicin [Dificid]) treatment for recurrent *Clostridioides difficile* infection (CDI: a bacterial infection) (defined as at least 3 CDI episodes)
E. If you have previously been treated with Vowst, approval also requires:
   1. You had treatment failure, defined as the presence of *Clostridioides difficile* infection (CDI: a bacterial infection) diarrhea within 8 weeks of the first dose of Vowst, AND a positive stool test for *C. difficile* (a type of bacteria)
   2. You have NOT previously received more than 1 treatment course of Vowst AND the start of that treatment course was at least 12 days and not more than 8 weeks prior

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vowst.

REFERENCES

Vowst [Prescribing Information]. Bridgewater, NJ: Aimmune Therapeutics, Inc.; February 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FECAL MICROBIOTA SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FECAL MICROBIOTA, LIVE-JSLM	REBYOTA	48488		GPI-10 (5252201030)	

GUIDELINES FOR USE

1. Is the request for the prevention of recurrent *Clostridioides difficile* infection (CDI) (ICD-10 A04.71) and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist or infectious disease specialist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received treatment with Rebyota?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient completed antibiotic treatment (e.g., vancomycin [Vancocin]) for the treatment of recurrent CDI (defined as at least 3 CDI episodes) at least 24 hours prior?

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #150mL.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient had treatment failure, defined as the presence of CDI diarrhea within 8 weeks of the first dose of Rebyota, AND a positive stool test for *C. difficile*
   - The patient has NOT previously received more than 1 dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill with a quantity limit of #150mL.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FECAL MICROBIOTA SUSPENSION

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FECAL MICROBIOTA SUSPENSION (Rebyota)** requires the following rule(s) be met for approval:

A. Rebyota will be used for the prevention of recurrent *Clostridioides difficile* (*C. difficile*) infection (CDI: a bacterial infection)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or infectious disease specialist (a doctor who specializes in the treatment of infections)
D. If you have NOT previously been treated with Rebyota, approval also requires:
   1. You have completed antibiotic (such as vancomycin [Vancocin]) treatment for recurrent *Clostridioides difficile* infection (CDI: a bacterial infection) (defined as at least 3 CDI episodes) at least 24 hours prior
E. If you have previously been treated with Rebyota, approval also requires:
   1. You had treatment failure, defined as the presence of *Clostridioides difficile* infection (CDI: a bacterial infection) diarrhea within 8 weeks of the first dose of Rebyota, AND a positive stool test for *C. difficile* (a type of bacteria)
   2. You have NOT previously received more than 1 dose of Rebyota AND that dose was at least 7 days and not more than 8 weeks prior

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rebyota.

REFERENCES

Rebyota [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; November 2022.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FEDRATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FEDRATINIB DIHYDROCHLORIDE	INREBIC	45953		GPI-10 (2153752020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) (ICD-10 D47.1, D75.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to Jakafi (ruxolitinib)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for approval:
   A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) Jakafi (ruxolitinib)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FEDRATINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) (ICD-10 D47.1, D75.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has a spleen volume reduction of at least 35% from baseline
   - The patient has at least a 50% reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has at least a 50% reduction in palpable spleen length

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for renewal:
   A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera [type of blood cell disorder] or post-essential thrombocythemia [type of blood cell disorder]) myelofibrosis (type of bone marrow cancer)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have a spleen volume reduction of at least 35% from baseline (before treatment)
      2. You have at least a 50% reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      3. You have at least a 50% reduction in palpable (can be felt by external examination) spleen length

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FEDRATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inrebic.

REFERENCES

Inrebic [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; May 2025.

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FENFLURAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENFLURAMINE HCL	FINTEPLA	02116		GPI-10 (7260002810)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome (ICD-10 Group G40.83) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to ONE of the following: valproic acid derivative, clobazam

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) (ICD-10 Group G40.81) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to valproic acid or derivatives
   - The patient had a trial of or contraindication to TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FENFLURAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:

A. You have seizures associated with ONE of the following:
   1. Dravet syndrome (a rare type of seizure)
   2. Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)

B. If you have Dravet syndrome, approval also requires:
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following: valproic acid derivative, clobazam

C. If you have Lennox-Gastaut syndrome, approval also requires:
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   3. You have tried or have a contraindication to (harmful for you to use) valproic acid or derivatives
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following: Epidiolex, rufinamide, felbamate, clobazam, topiramate, lamotrigine, clonazepam

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FENFLURAMINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome (ICD-10 Group G40.83)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) (ICD-10 Group G40.81)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for renewal:
   A. You have seizures associated with ONE of the following:
      1. Dravet syndrome (a rare type of seizure)
      2. Lennox-Gastaut syndrome (LGS: a type of seizure disorder in young children)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fintepla.

REFERENCES

Fintepla [Prescribing Information]. Smyrna, GA: UCB, Inc., April 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FENTANYL TRANSDERMAL PATCH

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL	DURAGESIC, FENTANYL		24635 19200 37952 19201 37947 19202 37948 19203	GPI-12 (651000250086)	

GUIDELINES FOR USE

1. Does the patient meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose of another opioid)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the request form indicate that this medication will be used on an "as needed" or “PRN” basis?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

3. Is the request for every 72 hours dosing?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **FOR EVERY 72 HOUR DOSING (12, 25, 37.5, 50, 62.5, 75, 87.5mcg/hr): #10 patches per 30 days.**
   - **FOR 100mcg/hr: up to #20 patches per 30 days.**

   If no, continue to #4.

4. Is the request for every 48 hours dosing?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FENTANYL TRANSDERMAL PATCH

GUIDELINES FOR USE (CONTINUED)

5. Has the patient tried every 72 hours dosing?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **FOR EVERY 48 HOUR DOSING (12, 25, 37.5, 50, 62.5, 75, 87.5mcg/hr): #15 patches per 30 days.**
   - **FOR 100mcg/hr: up to #30 patches per 30 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FENTANYL TRANSDERMAL PATCH (Duragesic)** requires the following rule(s) be met for approval:
   A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose (equal pain-relieving dose) of another opioid
   B. The requested medication is not prescribed on an 'as needed' basis
   C. Requests for every 48 hours dosing requires a trial of transdermal (absorbed through the skin) fentanyl patch dosed every 72 hours

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Duragesic.

REFERENCES

Fentanyl Patch [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; March 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 02/03
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FENTANYL TRANSMUCOSAL AGENTS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENTANYL CITRATE	ACTIQ, FENTANYL CITRATE	01747		GPI-10 (6510002510)	FDB & Medi-Span: ROUTE = BUCCAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer-related pain (ICD-10 G89.3) and meet **ALL** of the following criteria?
   - The patient is on a maintenance dose of a controlled-release pain medication (e.g., MS Contin [morphine extended-release], Oxycontin [oxycodone extended-release], Duragesic [fentanyl patch])
   - The patient has difficulty swallowing tablets or capsules, OR the patient had a trial of or contraindication to ONE clinical standard of care immediate-release oral pain agent (e.g., morphine sulfate immediate-release [MSIR], oxycodone/acetaminophen, hydrocodone/acetaminophen, codeine/acetaminophen, hydromorphone, meperidine)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for generic fentanyl citrate lozenge?

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with a quantity limit of #120 per month.**

   If no, continue to #3.

3. Has the patient had a trial of or contraindication to the preferred agent: generic fentanyl citrate lozenge?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #120 per month.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FENTANYL TRANSMUCOSAL AGENTS

GUIDELINES FOR USE (CONTINUED

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FENTANYL TRANSMUCOSAL AGENTS (Actiq)** requires the following rule(s) be met for approval:

A. You have cancer-related pain
B. You are on a maintenance dose of a controlled-release pain medication (such as MS Contin [morphine extended-release], Oxycontin [oxycodone extended-release], Duragesic [fentanyl patch])
C. You have difficulty swallowing tablets or capsules, OR you have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care oral immediate- release pain medication (such as morphine sulfate immediate-release [MSIR], oxycodone/acetaminophen, hydrocodone/acetaminophen, codeine/acetaminophen, hydromorphone, meperidine)
D. You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic fentanyl citrate lozenge (which also requires a prior authorization)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actiq.

REFERENCES

Actiq [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; December 2025.

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FILGRASTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM	NEUPOGEN	06070		GPI-10 (8240152000)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient undergone or is undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient undergoing autologous peripheral blood progenitor cell collection and therapy, and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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FILGRASTIM

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9), and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM (Neupogen)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. You have undergone or are undergoing induction or consolidation chemotherapy (starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
   3. You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood- forming cells), and you have a non-myeloid malignancy (cancer not affecting the bone marrow)
   4. You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic syndrome of acute radiation syndrome [H- ARS]: an illness that happens after whole body radiation)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neupogen.

REFERENCES

Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Created: 08/21
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/23

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FILGRASTIM-AAFI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-AAFI	NIVESTYM	45154		GPI-10 (8240152010)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient undergone or is undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) **AND** meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient undergoing autologous peripheral blood progenitor cell collection and therapy, **AND** meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

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FILGRASTIM-AAFI

GUIDELINES FOR USE (CONTINUED)

6. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]) **AND** meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FILGRASTIM-AAFI (Nivestym)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have a non-myeloid malignancy (cancer not affecting bone marrow)
      2. You have undergone or are undergoing induction or consolidation chemotherapy (starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
      3. You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood- forming cells), and you have a non-myeloid malignancy (cancer not affecting bone marrow)
      4. You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)
      5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles or due to unknown cause)
      6. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic syndrome of acute radiation syndrome [H- ARS]: an illness that happens after whole body radiation)
   B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FILGRASTIM-AAFI

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nivestym and Neupogen.

REFERENCES

Nivestym [Prescribing Information]. Lake Forest, IL: Pfizer; February 2024.
Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Created: 10/22
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/23

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FILGRASTIM-AYOW

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-AYOW	RELEUKO	47848		GPI-10 (8240152015)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient undergone or is undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient undergoing autologous peripheral blood progenitor cell collection and therapy, and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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FILGRASTIM-AYOW

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM-AYOW

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM-AYOW (Releuko)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have a non-myeloid malignancy (cancer not affecting the bone marrow)
   2. You have undergone or are undergoing induction or consolidation chemotherapy (starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
   3. You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood- forming cells), and you have a non-myeloid malignancy (cancer not affecting the bone marrow)
   4. You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low amount of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic syndrome of acute radiation syndrome [H- ARS]: an illness that happens after whole body radiation)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Releuko and Neupogen.

REFERENCES

Releuko [Prescribing Information]. Piscataway, NJ: Kashiv BioSciences, LLC; September 2023.
Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Created: 05/22
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FILGRASTIM-SNDZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-SNDZ	ZARXIO	41814		GPI-10 (8240152060)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient undergone or is undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient undergoing autologous peripheral blood progenitor cell collection and therapy, and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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FILGRASTIM-SNDZ

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9), and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FILGRASTIM-SNDZ

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FILGRASTIM-SNDZ (Zarxio)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. You have undergone or are undergoing induction or consolidation chemotherapy (starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
   3. You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood- forming cells), and you have a non-myeloid malignancy (cancer not affecting bone marrow)
   4. You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)
   5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown cause)
   6. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic syndrome of acute radiation syndrome [H- ARS]: an illness that happens after whole body radiation)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

C. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zarxio and Neupogen.

REFERENCES

Zarxio [Prescribing Information]. Princeton, NJ: Sandoz Inc.; October 2024.
Neupogen [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; April 2023.

Created: 10/22
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FILGRASTIM-TXID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FILGRASTIM-TXID	NYPOZI	49813		GPI-10 (8240152075)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever and meet **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient undergone or is undergoing induction or consolidation chemotherapy treatment for acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10**.
   If no, continue to #3.

3. Is the patient undergoing myeloablative chemotherapy followed by bone marrow transplantation and meet **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient undergoing autologous peripheral blood progenitor cell collection and therapy and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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FILGRASTIM-TXID

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of congenital neutropenia (ICD-10 D70.0), cyclic neutropenia (ICD-10 D70.4), or idiopathic neutropenia (ICD-10 D70.9), and meet ALL of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Has the patient been acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to the preferred medication: Nivestym (filgrastim-aafi)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FILGRASTIM-TXID (Nypozi)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever, and you have non-myeloid malignancy (cancer not affecting the bone marrow)
      2. You have undergone or are undergoing induction or consolidation chemotherapy (you are starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: a type of blood cancer)
      3. You are undergoing myeloablative chemotherapy (high-dose medications used to treat cancer) followed by bone marrow transplantation (procedure to get healthy blood- forming cells), and you have non-myeloid malignancy (cancer not affecting the bone marrow)
      4. You are undergoing autologous peripheral blood progenitor cell collection and therapy (a type of blood cancer treatment)

   (Denial text continued on the next page)

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FILGRASTIM-TXID

GUIDELINES FOR USE (CONTINUED)

5. You have congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia (low levels of a type of white blood cell at birth, in cycles, or due to unknown causes)
6. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H- ARS]: an illness that happens after whole body radiation)

B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
C. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Nivestym (filgrastim-aafi)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nypozi.

REFERENCES
Nypozi [Prescribing Information]. San Diego, CA: Tanvex BioPharma USA, Inc.; June 2024.

Created: 11/24
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FINGOLIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINGOLIMOD	GILENYA, FINGOLIMOD	37180		GPI-10 (6240702510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 10 years of age or older

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ANY** of the following contraindications to Gilenya?
   - A recent (within the past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   - A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker
   - A baseline QTc interval of 500 msec or above
   - Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

     If yes, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

     If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

     DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **FINGOLIMOD (Gilenya)** requires the following rule(s) be met for approval:
     A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)

(Denial text continued on next page)

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FINGOLIMOD

GUIDELINES FOR USE (CONTINUED)

B. You are 10 years of age or older
C. You do NOT have ANY of the following contraindications to (harmful for you to use) Gilenya:
   1. A recent (within the past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke (a type of brain damage), transient ischemic attack (a type of stroke), decompensated heart failure (a type of heart condition) requiring hospitalization, or Class III/IV heart failure (a type of heart condition)
   2. A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)
   3. A baseline QTc interval of 500 msec or above (a measure of the speed of electrical conduction in the heart)
   4. Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gilenya.

REFERENCES

Gilenya [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceutical Corporation; August 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/24
Created: 11/10
Client Approval: 05/24
P&T Approval: 07/18

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FINGOLIMOD LAURYL SULFATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FINGOLIMOD LAURYL SULFATE	TASCENSO ODT	48165		GPI-10 (6240702520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient has a contraindication to or is unable to swallow fingolimod oral capsules

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ANY** of the following contraindications to Tascenso ODT?
   - A recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   - A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker
   - A baseline QTc interval of at least 500 msec
   - Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

3. Is the patient 18 years of age or older?

   If yes, continue to #4.
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

4. Has the patient had a trial of or contraindication to TWO of the following preferred agents: Zeposia (ozanimod), fingolimod (Gilenya), dimethyl fumarate (Tecfidera), Vumerity (diroximel fumarate), Mayzent (siponimod)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FINGOLIMOD LAURYL SULFATE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FINGOLIMOD LAURYL SULFATE (Tascenso ODT)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
B. You are 10 years of age or older
C. You have a contraindication to (harmful for you to use) or are unable to swallow oral fingolimod oral capsules
D. You do NOT have any of the following contraindications to (harmful for you to use) Tascenso ODT:
    1. A recent (within past 6 months) occurrence of myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
    2. A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome (types of irregular heartbeats), unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)
    3. A baseline QTc interval of at least 500 msec (a measure of the speed of electrical conduction in the heart)
    4. Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)
E. If you are 18 years of age or older, approval also requires:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Zeposia (ozanimod), fingolimod (Gilenya), dimethyl fumarate (Tecfidera), Vumerity (diroximel fumarate), Mayzent (siponimod)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tascenso ODT.

REFERENCES

Tascenso ODT [Prescribing Information]. San Jose, CA: Handa Neuroscience, LLC; January 2025.

Created: 11/22
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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FITUSIRAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FITUSIRAN SODIUM	QFITLIA	50406		GPI-10 (8510072520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemophilia A (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Qfitlia will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   - Therapy is prescribed by or in consultation with a hematologist
   - Qfitlia will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of hemophilia B (ICD-10 D67) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Qfitlia will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   - Therapy is prescribed by or in consultation with a hematologist
   - Qfitlia will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FITUSIRAN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FITUSIRAN (Qfitlia)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hemophilia A (a type of bleeding disorder)
   2. Hemophilia B (a type of bleeding disorder)

B. If you have hemophilia A, approval also requires:
   1. You are 12 years of age or older
   2. Qfitlia will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   3. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   4. You will NOT use Qfitlia concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

C. If you have hemophilia B, approval also requires:
   1. You are 12 years of age or older
   2. Qfitlia will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   3. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   4. You will NOT use Qfitlia concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FITUSIRAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline
   - Qfitlia will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of hemophilia B (ICD-10 D67) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline
   - Qfitlia will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FITUSIRAN (Qfitlia)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Hemophilia A (a type of bleeding disorder)
      2. Hemophilia B (a type of bleeding disorder)

   B. If you have hemophilia A, renewal also requires:
      1. You have shown a clinical benefit compared to baseline (before starting Qfitlia)
      2. You will NOT use Qfitlia concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

   C. If you have hemophilia B, renewal also requires:
      1. You have shown a clinical benefit compared to baseline (before starting Qfitlia)
      2. You will NOT use Qfitlia concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh], Hympavzi [marstacimab-hncq], Alhemo [concizumab-mtci])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FITUSIRAN

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Qfitlia.

REFERENCES
Qfitlia [Prescribing Information]. Cambridge, MA: Genzyme Corporation; March 2025.

Created: 04/25
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 01/25

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FLIBANSERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FLIBANSERIN	ADDYI	42447		GPI-10 (6217503000)	FDB: ROUTE ≠ MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Is Addyi (flibanserin) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptom cause marked distress or interpersonal difficulty

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is a female
   - The patient is 18 to 64 years of age
   - The patient had a previous trial of or contraindication to bupropion
   - The patient is not currently using Vyleesi (bremelanotide)

   If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FLIBANSERIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FLIBANSERIN (Addyi)** requires the following rule(s) be met for approval:

A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by ALL of the following criteria:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty
B. You are a female
C. You are 18 to 64 years of age
D. You previously had a trial of bupropion, unless there is a medical reason why you cannot (contraindication)
E. You are not currently using Vyleesi (bremelanotide)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FLIBANSERIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
   - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   - HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
   - HSDD symptoms cause marked distress or interpersonal difficulty

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is a female
   - The patient is not currently using Vyleesi
   - The patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)?

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **FLIBANSERIN (Addyi)** requires the following rule(s) be met for renewal:
   A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
      1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
      2. Hypoactive sexual desire disorder is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
      3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty

   (Renewal denial text continued on next page)

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FLIBANSERIN

RENEWAL CRITERIA (CONTINUED)

B. You are a female
C. You are not currently using Vyleesi (bremelanotide)
D. You have demonstrated continued improvement in symptoms of hypoactive sexual desire disorder/female sexual interest and arousal disorder (such as increased sexual desire, lessened distress)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Addyi.

REFERENCES
Addyi [Prescribing Information]. Raleigh, NC: Sprout Pharmaceuticals, Inc.; October 2019.

Created: 09/15
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 01/26

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FLUOROURACIL CREAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FLUOROURACIL	CARAC, FLUOROURACIL		12514	GPI-14 (90372030003705)	
FLUOROURACIL	FLUOROPLEX		30780	GPI-14 (90372030003710)	

**** Please use the criteria for the specific drug requested ****

GUIDELINE FOR USE

CARAC

1. Does the patient have a diagnosis of actinic or solar keratosis (AK) (ICD-10 L57.0) and meet **ALL** of the following criteria?
   - The patient has actinic or solar keratosis on the face or anterior scalp
   - The patient had a trial of TWO preferred generic topical agents indicated for AK (e.g., fluorouracil 5%, imiquimod, diclofenac 3%)

   If yes, **approve for 1 month by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FLUOROURACIL CREAM (Carac)** requires the following rule(s) be met for approval:
   A. You have actinic or solar keratosis (AK: a type of skin condition)
   B. You have actinic or solar keratosis on the face or anterior (front) scalp
   C. You have tried TWO preferred generic topical (applied to skin) medications for AK (such as fluorouracil 5%, imiquimod, diclofenac 3%)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FLUOROURACIL CREAM

FLUOROPLEX

1. Does the patient have a diagnosis of actinic or solar keratosis (AK) (ICD-10 L57.0) **AND** meet the following criterion?
   - The patient had a trial of TWO preferred generic topical agents indicated for AK (e.g., fluorouracil, imiquimod, diclofenac 3%)

   If yes, **approve for 1 month by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FLUOROURACIL CREAM (Fluoroplex)** requires the following rule(s) be met for approval:
   A. You have actinic or solar keratosis (AK: a type of skin condition)
   B. You have tried TWO preferred generic topical (applied to skin) medications for AK (such as fluorouracil, imiquimod, diclofenac 3%)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Carac or Fluoroplex.

REFERENCES
Carac [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; December 2024.
Fluoroplex [Prescribing Information]. Exton, PA: Almirall, LLC.; March 2022.

Created: 08/18
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 04/21

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FOSCARBIDOPA-FOSLEVODOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSCARBIDOPA/ FOSLEVODOPA	VYALEV	49183		GPI-10 (7320990213)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?
   - Vyalev is being used for the treatment of motor fluctuations associated with Parkinson's disease
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient's disease is responsive to treatment with levodopa
   - The patient is currently being treated with at least 400mg of levodopa per day
   - The patient has motor symptoms that are currently uncontrolled (defined as an average 'off' time of at least 2.5 hours per day over 3 consecutive days, with a minimum of 2 hours each day)

   If yes, continue to #2.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is unable to swallow extended-release tablets or administer extended-release capsules via a feeding tube
   - The patient has failed to adhere to an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen via a feeding tube

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #20mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FOSCARBIDOPA-FOSLEVODOPA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSCARBIDOPA-FOSLEVODOPA (Vyalev)** requires the following rule(s) be met for approval:

A. You have advanced Parkinson's disease (PD: a type of movement disorder)
B. Vyalev will be used for the treatment of motor fluctuations (changes in the ability to move) associated with Parkinson's disease
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
D. Your disease is responsive to treatment with levodopa
E. You are currently being treated with at least 400mg of levodopa per day
F. Your motor symptoms are currently uncontrolled (defined as an average 'off' time of at least 2.5 hours per day over 3 consecutive days, with a minimum of 2 hours each day)
G. You meet ONE of the following:
    1. You are unable to swallow extended-release tablets or administer extended-release capsules through a feeding tube
    2. You have failed to adhere to (keep up with) an oral carbidopa/levodopa regimen or tolerate a carbidopa/levodopa regimen through a feeding tube

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FOSCARBIDOPA-FOSLEVODOPA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced Parkinson's disease (PD) (ICD-10 Group G20) **AND** meet the following criterion?

- The patient has experienced improvement in motor symptoms while on Vyalev

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #20mL per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FOSCARBIDOPA-FOSLEVODOPA (Vyalev)** requires the following rule(s) be met for renewal:
A. You have advanced Parkinson's disease (PD: a type of movement disorder)
B. You have experienced improvement in motor symptoms with the use of Vyalev

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyalev.

REFERENCES

Vyalev [Prescribing Information]. North Chicago, IL: AbbVie Inc.; October 2024.

Created: 10/24
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSDENOPTERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSDENOPTERIN HYDROBROMIDE	NULIBRY	47158		GPI-10 (3090643020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of molybdenum cofactor deficiency (MoCD) Type A (ICD-10 E61.5)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSDENOPTERIN (Nulibry)** requires the following rule(s) be met for approval:
   A. You have molybdenum cofactor deficiency (MoCD) Type A (a type of rare genetic condition)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nulibry.

REFERENCES

Nulibry [Prescribing Information]. Solana Beach, CA: Sentynl Therapeutics, Inc.; October 2022.

Created: 05/21
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSTAMATINIB DISODIUM	TAVALISSE	44895		GPI-10 (8575604010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to corticosteroids or immunoglobulins, OR had an insufficient response to a splenectomy
   - The patient has a platelet count of less than 30 x 10^9/L, OR has a platelet count of less than 50 x 10^9/L and a prior bleeding event
   - Tavalisse will NOT be used concurrently with a Bruton's tyrosine kinase (BTK) inhibitor (e.g., Wayrilz [rilzabrutinib]) for the treatment of cITP

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for approval:
   A. You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) corticosteroids or immunoglobulins, OR you did not have a good enough response to a splenectomy (spleen removal)
   D. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L, OR you have a platelet count of less than 50 x 10^9/L AND had a prior bleeding event
   E. You will NOT use Tavalisse concurrently (at the same time) with a Bruton's tyrosine kinase (BTK) inhibitor (such as Wayrilz [rilzabrutinib]) for the treatment of chronic immune thrombocytopenia

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events
   - Tavalisse will NOT be used concurrently with a Bruton's tyrosine kinase (BTK) inhibitor (e.g., Wayrilz [rilzabrutinib]) for the treatment of cITP

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for renewal:
   A. You have chronic immune thrombocytopenia (cITP: a type of blood disorder)
   B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Tavalisse) OR a decrease in bleeding events
   C. You will NOT use Tavalisse concurrently (at the same time) with a Bruton's tyrosine kinase (BTK) inhibitor (such as Wayrilz [rilzabrutinib]) for the treatment of chronic immune thrombocytopenia

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tavalisse.

REFERENCES

Tavalisse [Prescribing Information]. South San Francisco, CA: Rigel Pharmaceuticals, Inc; December 2024.

Created: 08/18
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FOSTEMSAVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSTEMSAVIR TROMETHAMINE	RUKOBIA	46684		GPI-10 (1210233040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection (ICD-10 B20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Rukobia will be used in combination with other antiretroviral(s)
   - The patient is treatment-experienced
   - The patient's HIV-1 infection is multidrug-resistant
   - The patient is failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FOSTEMSAVIR (Rukobia)** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus type 1 (HIV-1) infection (an immune system disease caused by a virus)
   B. You are 18 years of age or older
   C. Rukobia will be used in combination with other antiretroviral(s) (medications that treat HIV)
   D. You are treatment-experienced (previously treated)
   E. Your HIV-1 infection is multidrug-resistant (does not respond to more than one HIV medication)
   F. You are failing your current antiretroviral regimen due to resistance (does not respond), intolerance (side effect), or safety considerations

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rukobia.

REFERENCES

Rukobia [Prescribing Information]. Durham, NC: ViiV Healthcare; February 2024.

Created: 07/20
Effective: 02/01/26 Client Approval: 04/25 P&T Approval:07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FREMANEZUMAB-VFRM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FREMANEZUMAB-VFRM	AJOVY	45236		GPI-10 (6770203020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Ajovy is prescribed for the preventive treatment of migraines
   - Ajovy will NOT be used concurrently with other CGRP inhibitors (e.g., Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines (ICD-10 Group G43.7, G43.E) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ajovy is prescribed for the preventive treatment of migraines
   - Ajovy will NOT be used concurrently with other CGRP inhibitors (e.g., Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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FREMANEZUMAB-VFRM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Episodic migraines (a type of headache)
   2. Chronic migraines (a type of headache)

B. If you have episodic migraines (0-14 headache days per month), approval also requires:
   1. You are 6 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines (a type of headache)
   3. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention

C. If you have chronic migraines (at least 15 headache days per month), approval also requires:
   1. You are 18 years of age or older
   2. Ajovy is prescribed for the preventive treatment of migraines (a type of headache)
   3. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FREMANEZUMAB-VFRM

RENEWAL CRITERIA

1. Is the request for the preventive treatment of migraines **AND** the patient meets the following criterion?
   - Ajovy will NOT be used concurrently with other CGRP inhibitors (e.g., Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
   - The patient has experienced a reduction in migraine severity with Ajovy therapy
   - The patient has experienced a reduction in migraine duration with Ajovy therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for renewal:
   A. The request is for the preventive treatment of migraines (a type of headache)
   B. You will NOT use Ajovy concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant], Qulipta [atogepant]) for migraine (a type of headache) prevention
   C. You meet ONE of the following:
      1. You have experienced a decrease in migraine (a type of headache) or headache frequency of at least 2 days per month with Ajovy therapy
      2. You have experienced a decrease in migraine (a type of headache) severity with Ajovy therapy
      3. You have experienced a decrease in migraine (a type of headache) duration with Ajovy therapy

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FREMANEZUMAB-VFRM

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ajovy.

REFERENCES
Ajovy [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; August 2025.

Created: 09/18
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FRUQUINTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FRUQUINTINIB	FRUZAQLA	47169		GPI-10 (2133503500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, CapeOx)
   - The patient has received previous treatment with an anti-VEGF therapy (e.g., Zaltrap [ziv-aflibercept], Cyramza [ramucirumab])

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **1mg: #84 per 28 days.**
   - **5mg: #21 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FRUQUINTINIB (Fruzaqla)** requires the following rule(s) be met for approval:
   A. You have metastatic colorectal cancer (mCRC: a type of digestive system cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You have received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, CapeOx)
   D. You have received previous treatment with an anti- vascular endothelial growth factor (VEGF) therapy (a type of treatment such as Zaltrap [ziv-aflibercept], Cyramza [ramucirumab])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FRUQUINTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fruzaqla.

REFERENCES

Fruzaqla [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals America, Inc.; February 2025.

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FULVESTRANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FULVESTRANT	FASLODEX FULVESTRANT	23523		GPI-10 (2140353000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's cancer hormone receptor (HR)-positive and the patient meets **ALL** of the following criteria?
   - The patient's cancer is advanced
   - The patient is a female and postmenopausal
   - The requested medication will be used as monotherapy
   - The patient has experienced disease progression following an endocrine therapy (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve for a total of 12 months by HICL or GPI-10. Enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #30mL per 30 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #10mL per 30 days (please enter a start date of THREE WEEKS AFTER the end date of the first approval).**

   If no, continue to #3.

3. Is the patient's cancer HR-positive **AND** human epidermal growth factor receptor 2 (HER2)-negative?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FULVESTRANT

GUIDELINES FOR USE (CONTINUED)

4. Will the requested medication be used as monotherapy and the patient meets **ALL** of the following criteria?
   - The patient's cancer is advanced
   - The patient is a female and postmenopausal
   - The patient has NOT been previously treated with an endocrine therapy (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve for a total of 12 months by HICL or GPI-10. Enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #30mL per 30 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #10mL per 30 days (please enter a start date of THREE WEEKS AFTER the end date of the first approval).**

   If no, continue to #5.

5. Will the requested medication be used in combination with Kisqali (ribociclib) and the patient meets **ALL** of the following criteria?
   - The patient's cancer is advanced or metastatic
   - The patient is a female and postmenopausal
   - The patient has NOT received a prior endocrine based therapy (e.g., letrozole, anastrozole, tamoxifen) OR the patient has experienced disease progression on endocrine therapy

   If yes, **approve for a total of 12 months by HICL or GPI-10. Enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #30mL per 30 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #10mL per 30 days (please enter a start date of THREE WEEKS AFTER the end date of the first approval).**

   If no, continue to #6.

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FULVESTRANT

GUIDELINES FOR USE (CONTINUED)

6. Will the requested medication be used in combination with Itovebi (inavolisib) and Ibrance (palbociclib) and the patient meets **ALL** of the following criteria?
   - The patient's cancer is locally advanced or metastatic
   - The patient's tumor has a PIK3CA mutation, as detected by an FDA-approved test
   - The patient has experienced disease recurrence on or after completing an adjuvant endocrine therapy (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve for a total of 12 months by HICL or GPI-10. Enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #30mL per 30 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #10mL per 30 days (please enter a start date of THREE WEEKS AFTER the end date of the first approval).**

   If no, continue to #7.

7. Will the requested medication be used in combination with Ibrance (palbociclib) or Verzenio (abemaciclib) and the patient meets **ALL** of the following criteria?
   - The patient's cancer is advanced or metastatic
   - The patient is a female
   - The patient has experienced disease progression after an endocrine therapy (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve for a total of 12 months by HICL or GPI-10. Enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #30mL per 30 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #10mL per 30 days (please enter a start date of THREE WEEKS AFTER the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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FULVESTRANT

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FULVESTRANT (Faslodex)** requires the following rule(s) be met for approval:

A. You have breast cancer

B. If you have hormone receptor (HR: a type of protein)-positive breast cancer, approval also requires:
1. Your cancer is advanced
2. You are a female and postmenopausal (after menopause)
3. The requested medication will be used as monotherapy (one medication treatment)
4. You have experienced disease progression (worsening) following endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)

C. If you have hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative breast cancer, approval also requires ONE of the following:
1. The requested medication will be used as monotherapy (one medication treatment) and you meet ALL of the following:
   a. Your cancer is advanced
   b. You are a female and postmenopausal (after menopause)
   c. You have NOT previously been treated with an endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)
2. The requested medication will be used in combination with Kisqali (ribociclib) and you meet ALL of the following:
   a. Your cancer is advanced or metastatic (has spread to other parts of the body)
   b. You are a female and postmenopausal
   c. You have NOT received a prior endocrine based therapy (such as letrozole, anastrozole, tamoxifen) OR you have experienced disease progression (worsening) on endocrine therapy
3. The requested medication will be used in combination with Itovebi (inavolisib) and Ibrance (palbociclib) and you meet ALL of the following:
   a. Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   b. Your tumor has a PIK3CA mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   c. You have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)

(Denial text continued on the next page)

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FULVESTRANT

GUIDELINES FOR USE (CONTINUED)

4. The requested medication will be used in combination with Ibrance (palbociclib) or Verzenio (abemaciclib) and you meet ALL of the following:
   a. Your cancer is advanced or metastatic
   b. You are a female
   c. You have experienced disease progression after an endocrine therapy (such as letrozole, anastrozole, tamoxifen)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Faslodex.

REFERENCES

Faslodex [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2021.
Itovebi [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; October 2024.
Ibrance [Prescribing Information]. New York, NY: Pfizer Laboratories; April 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FUROSEMIDE-FUROSCIX READYFLOW

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FUROSEMIDE	FUROSCIX READYFLOW		59494	GPI-14 (3720003000D520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of edema (ICD-10 Group R60) with chronic heart failure or chronic kidney disease (including nephrotic syndrome) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or nephrologist

   If yes, **approve for 30 days by GPID or GPI-14 for #1 fill.**
   If no, do not approve.

   DENIAL TEXT: Our guideline named **FUROSEMIDE-FUROSCIX READYFLOW** requires the following rule(s) be met for approval:
   A. You have edema (swelling caused by fluid build-up in the body) with chronic (long-term) heart failure (a type of heart condition) or chronic kidney disease (including nephrotic syndrome [a type of kidney disorder])
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or nephrologist (a type of kidney doctor)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Furoscix Readyflow.

REFERENCES

Furoscix Readyflow [Prescribing Information]. Burlington, MA: MannKind Corporation; July 2026.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FUROSEMIDE - LASIX ONYU

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FUROSEMIDE	LASIX ONYU	03660		GPI-10 (3720003000)	BRAND = LASIX ONYU

GUIDELINES FOR USE

1. Does the patient have a diagnosis of edema (ICD-10 Group R60) with chronic heart failure and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or nephrologist

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FUROSEMIDE - LASIX ONYU** requires the following rule(s) be met for approval:
   A. You have edema (swelling caused by fluid build-up in the body) with chronic (long-term) heart failure (a type of heart condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or nephrologist (a type of kidney doctor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lasix Onyu.

REFERENCES

Lasix Onyu. [Prescribing Information]. Burlington, MA: SQ Innovation, Inc.; October 2025.

Created: 11/25
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

FUROSEMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FUROSEMIDE	FUROSCIX		52993	GPI-14 (3720003000F720)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of edema (ICD-10 Group R60) with chronic heart failure or chronic kidney disease (including nephrotic syndrome) and meet **ALL** of the following criteria?
   - The patient weighs at least 43 kg (94.6 lbs)
   - Therapy is prescribed by or in consultation with a cardiologist or nephrologist

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #1 for 1 fill.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FUROSEMIDE (Furoscix)** requires the following rule(s) be met for approval:
   A. You have edema (swelling caused by fluid build-up in the body) with chronic (long-term) heart failure (a type of heart condition) or chronic kidney disease (including nephrotic syndrome [a type of kidney disorder])
   B. You weigh at least 43 kilograms (94.6 pounds)
   C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or nephrologist (a type of kidney doctor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Furoscix.

REFERENCES

Furoscix [Prescribing Information]. Burlington, MA: scPharmaceuticals, Inc.; December 2025.

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FUTIBATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FUTIBATINIB	LYTGOBI	48369		GPI-10 (2153222800)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) (ICD-10 C22.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated for unresectable, locally advanced or metastatic iCCA
   - The patient has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to the initiation of Lytgobi and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **FUTIBATINIB (Lytgobi)** requires the following rule(s) be met for approval:
   A. You have unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) (a type of bile duct cancer inside the liver that is unable to be removed by surgery, has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
   B. You are 18 years of age or older
   C. You have been previously treated for unresectable, locally advanced or metastatic iCCA
   D. You have fibroblast growth factor receptor 2 (FGFR2: a type of protein) gene fusions or other rearrangements
   E. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting Lytgobi and at the recommended scheduled times

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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FUTIBATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lytgobi.

REFERENCES

Lytgobi [Prescribing Information]. Princeton, NJ: Taiho Oncology, Inc.; April 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GABAPENTIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GABAPENTIN	NEURONTIN, GABAPENTIN		13235 33065 33066	GPI-14 (72600030002020)	

GUIDELINES FOR USE

1. Does the patient have a contraindication to or is the patient unable to swallow generic gabapentin capsules?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GABAPENTIN** requires the following rule(s) be met for approval:
   A. You have a contraindication to (harmful for you to use) or are unable to swallow generic gabapentin capsules

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neurontin.

REFERENCES

Neurontin [Prescribing Information]. New York, NY: Pfizer, Inc; July 2010.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GALANTAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GALANTAMINE HBR	GALANTAMINE HYDROBROMIDE		13898	GPI-14 (62051030102020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Alzheimer's disease (ICD-10 Group G30) and meet **ALL** of the following criteria?
   - The patient has mild to moderate dementia
   - The patient has a contraindication to or is unable to swallow galantamine tablets or capsules

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GALANTAMINE** requires the following rule(s) be met for approval:
   A. You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
   B. You have mild to moderate dementia (a type of memory disorder)
   C. You have a contraindication to (harmful for you to use) or are unable to swallow galantamine tablets or capsules

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for galantamine oral solution.

REFERENCES

Galantamine oral solution [Prescribing Information]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA, Inc.; October 2023.

Created: 05/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 01/26

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GALCANEZUMAB-GNLM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GALCANEZUMAB-GNLM	EMGALITY	45281		GPI-10 (6770203530)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Emgality is prescribed for the preventive treatment of migraines
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention

   If yes, **approve for 6 months by HICL or GPI-10.**
   (PAC Note: In addition, enter a one-time proactive PA for 120mg/mL strength by GPID or GPI-14 for 1 month with a quantity limit of #2mL per 30 days. Please override the quantity limit coded on the formulary by selecting the "QL Only" override.)

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines (ICD-10 Groups G43.7, G43.E) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Emgality is prescribed for the preventive treatment of migraines
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention

   If yes, **approve for 6 months by HICL or GPI-10.**
   (PAC Note: In addition, enter a one-time proactive PA for 120mg/mL strength by GPID or GPI-14 for 1 month with a quantity limit of #2mL per 30 days. Please override the quantity limit coded on the formulary by selecting the "QL Only" override.)

   If no, continue to #3.

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GALCANEZUMAB-GNLM

INITIAL CRITERIA (CONTINUED)

3. Is the request for the treatment of episodic cluster headache (ICD-10 Group G44.01) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's symptoms were NOT adequately managed with abortive therapies (e.g., Imitrex [sumatriptan], Zomig [zolmitriptan], oxygen)

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Episodic migraines (a type of headache)
      2. Chronic migraines (a type of headache)
      3. Episodic cluster headaches (a type of headache)

   B. If you have episodic migraines (0-14 headache days per month), approval also requires:
      1. You are 18 years of age or older
      2. Emgality is prescribed for the preventive treatment of migraines (a type of headache)
      3. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention

   (Initial denial text continued on next page)

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GALCANEZUMAB-GNLM

INITIAL CRITERIA (CONTINUED)

C. If you have chronic migraines (15 or more headache days per month), approval also requires:
1. You are 18 years of age or older
2. Emgality is prescribed for the preventive treatment of migraines (a type of headache)
3. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention

D. If you have episodic cluster headaches, approval also requires:
1. You are 18 years of age or older
2. Your symptoms were not adequately managed with abortive therapies (such as Imitrex [sumatriptan], Zomig [zolmitriptan], oxygen)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GALCANEZUMAB-GNLM

RENEWAL CRITERIA

1. Is the request for the preventive treatment of migraines **AND** the patient meets the following criterion?
   - Emgality will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
   - The patient has experienced a reduction in migraine severity with Emgality therapy
   - The patient has experienced a reduction in migraine duration with Emgality therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Is the request for the treatment of episodic cluster headache (ICD-10 Group G44.01) **AND** the patient meets the following criterion?
   - The patient had improvement in episodic cluster headache frequency as compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:
   A. The request is for ONE of the following:
      1. Preventive treatment of migraines (a type of headache)
      2. Treatment of episodic cluster headache (a type of headache)

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

B. If the request is for preventive treatment of migraines, renewal also requires:
1. You will NOT use Emgality concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Vyepti [eptinezumab-jjmr], Nurtec ODT [rimegepant orally disintegrating tablet], Qulipta [atogepant]) for migraine (a type of headache) prevention
2. You meet ONE of the following:
   a. You have experienced a decrease in migraine (a type of headache) or headache frequency of at least 2 days per month with Emgality therapy
   b. You have experienced a decrease in migraine (a type of headache) severity with Emgality therapy
   c. You have experienced a decrease in migraine (a type of headache) duration with Emgality therapy

C. If the request is for treatment of episodic cluster headaches, renewal also requires:
1. You had improvement in episodic cluster headache frequency as compared to baseline (before treatment)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing information and/or Drug Monograph for Emgality.

REFERENCES
Emgality [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; March 2025.

Created: 10/18
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GANAXOLONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GANAXOLONE	ZTALMY	47912		GPI-10 (7260003300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (ICD-10 Group G40.42) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #36 mL per day.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GANAXOLONE (Ztalmy)** requires the following rule(s) be met for approval:
   A. You have seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (a type of genetic disorder)
   B. You are 2 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ztalmy.

REFERENCES

Ztalmy [Prescribing Information]. Radnor, PA: Marinus Pharmaceuticals, Inc.; April 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GARADACIMAB-GXII

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GARADACIMAB-GXII	ANDEMBRY	50645		GPI-10 (8583203001)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Andembry will be used for prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Andembry will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo], Dawnzera [donidalorsen])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
- **FIRST APPROVAL: Approve for 1 month with a quantity limit of #2.4mL per 30 days.**
- **SECOND APPROVAL: Approve for 11 months with a quantity limit of #1.2mL per 30 days (Please enter a start date of 23 days AFTER the start date of the first approval).**

If no, continue to #3.

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GARADACIMAB-GXII

INITIAL CRITERIA (CONTINUED)

3. Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
   - The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
   - Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #2.4mL per 30 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #1.2mL per 30 days (Please enter a start date of 23 days AFTER the start date of the first approval).**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GARADACIMAB-GXII (Andembry)** requires the following rule(s) be met for approval:
   A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
   B. You are 12 years of age or older
   C. Andembry will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
   D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
   E. You will NOT use Andembry concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo], Dawnzera [donidalorsen])

(Initial denial text continued on next page)

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GARADACIMAB-GXII

INITIAL CRITERIA (CONTINUED)

F. You meet ONE of the following:
   1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
   2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
      a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
      b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GARADACIMAB-GXII

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?

- The patient has experienced an improvement in HAE attacks (reductions in attack frequency or attack severity) compared to baseline
- Andembry will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo], Dawnzera [donidalorsen])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.2mL per 30 days.** If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GARADACIMAB-GXII (Andembry)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema (a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
C. You will NOT use Andembry concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Takhzyro [lanadelumab-flyo], Dawnzera [donidalorsen])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Andembry.

REFERENCES

Andembry [Prescribing Information]. King of Prussia, PA: CSL Behring; June 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEFITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GEFITINIB	IRESSA, GEFITINIB	25178		GPI-10 (2136003000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient has tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations, as detected by an FDA-approved test
   - The requested medication will NOT be used concurrently with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (e.g., Tarceva [erlotinib], Tagrisso [osimertinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GEFITINIB (Iressa)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. Your tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (abnormal changes in a gene), as detected by a Food and Drug Administration (FDA)-approved test
   C. You will NOT use the requested medication concurrently (at the same time) with an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (such as Tarceva [erlotinib], Tagrisso [osimertinib], Gilotrif [afatinib], Vizimpro [dacomitinib])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Iressa.

REFERENCES

Iressa [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; February 2023.

Created: 07/15
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/22

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEMTUZUMAB OZOGAMICIN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GEMTUZUMAB OZOGAMICIN	MYLOTARG	21218		GPI-10 (2135363020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of newly-diagnosed CD33-positive acute myeloid leukemia (AML) and meet the following criterion?
   - The patient is 1 month of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory CD33-positive acute myeloid leukemia (AML) and meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GEMTUZUMAB OZOGAMICIN (Mylotarg)** requires that ONE of the following rule(s) be met for approval:
   1. You have newly-diagnosed CD33 (type of molecule that is used as a marker to diagnose AML) –positive acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many immature white blood cells) AND you are 1 month of age or older
   2. You have relapsed (returning) or refractory (resistant) CD33 (type of molecule that is used as a marker to diagnose AML) -positive acute myeloid leukemia (AML) AND you are 2 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mylotarg.

REFERENCES

Mylotarg [Prescribing Information]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; June 2020.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEMTUZUMAB OZOGAMICIN (NSA)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 09/17
Client Approval: 03/21
P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEPIRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GEPIRONE HCL	EXXUA	49298		GPI-10 (5812003010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of major depressive disorder (MDD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to BOTH of the following preferred agents: Fetzima (levomilnacipran) and Trintellix (vortioxetine)
   - Exxua will NOT be used concurrently with another 5-HT1A receptor agonist (e.g., buspirone)

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GEPIRONE (Exxua)** requires the following rule(s) be met for approval:
   A. You have major depressive disorder (MDD: a type of mental illness)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Fetzima (levomilnacipran) and Trintellix (vortioxetine)
   D. You will NOT use Exxua concurrently (at the same time) with another 5-HT1A receptor agonist (such as buspirone)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GEPIRONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of major depressive disorder (MDD) and meet **ALL** of the following criteria?
   - The patient has had a response to or remission of depressive symptoms with Exxua
   - Exxua will NOT be used concurrently with another 5-HT1A receptor agonist (e.g., buspirone)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GEPIRONE (Exxua)** requires the following rule(s) be met for renewal:
   A. You have major depressive disorder (MDD: a type of mental illness)
   B. You have had a response to or remission (reduction or disappearance of the signs and symptoms of a disease) of depressive symptoms with Exxua
   C. You will NOT use Exxua concurrently (at the same time) with another 5-HT1A receptor agonist (such as buspirone)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exxua.

REFERENCES

Exxua [Prescribing Information]. San Antonio, TX: Mission Pharmacal Company; September 2023.

Created: 10/25
Effective: 10/13/25 Client Approval: 10/25 P&T Approval: 04/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GEPOTIDACIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GEPOTIDACIN MESYLATE	BLUJEPA	50388		GPI-10 (1680001620)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of uncomplicated urinary tract infection (uUTI) (ICD-10 N39.0) and meet **ALL** of the following criteria?
   - The patient is a female
   - The patient is 12 years of age or older
   - The patient's infection is caused by susceptible *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, or Enterococcus faecalis*

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - Therapy is prescribed by or in consultation with an infectious disease (ID) specialist
   - The patient has a documented culture demonstrating uUTI is caused by a bacteria with sensitivity to gepotidacin AND resistance or contraindication to all alternatives (e.g. Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [e.g., amoxicillin-clavulanate], cephalosporins [e.g., cephalexin], fluoroquinolones [e.g., ciprofloxacin])
   - The request is for continuation of Blujepa therapy from an inpatient setting

   If yes, **approve for 5 days by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of uncomplicated urogenital gonorrhea (ICD-10 Group A54.0) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient's infection has limited or no alternative treatment options
   - The patient's infection is caused by a susceptible strain of *Neisseria gonorrhoeae*
   - The patient had a trial of or contraindication to the clinical standard of care agent: ceftriaxone

   If yes, **approve for 1 month by HICL or GPI-10 with a quantity limit of #8 for 1 fill (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GEPOTIDACIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GEPOTIDACIN (Blujepa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Uncomplicated urinary tract infection (uUTI: a type of bacterial infection)
   2. Uncomplicated urogenital gonorrhea (a type of bacterial infection)

B. If you have uncomplicated urinary tract infection, approval also requires:
   1. You are a female
   2. You are 12 years of age or older
   3. Your uncomplicated urinary tract infection (a type of bacterial infection) is caused by susceptible *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, or Enterococcus faecalis* (types of bacteria that can be treated with the medication)
   4. You meet ONE of the following:
      a. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
      b. You have a documented culture demonstrating uncomplicated urinary tract infection (a type of bacterial infection is caused by a bacteria with sensitivity (lab test that shows what medications work on which bacteria) to gepotidacin AND resistance (medication will not work for that bacteria) or contraindication to (harmful for you to use) all alternatives (such as Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [such as amoxicillin-clavulanate]], cephalosporins [such as cephalexin], fluoroquinolones [such as ciprofloxacin])
      c. Your request is for continuation of Blujepa therapy from an inpatient setting

C. If you have uncomplicated urogenital gonorrhea, approval also requires:
   1. You are 12 years of age or older
   2. Your infection has limited or no alternative treatment options
   3. Your infection is caused by a susceptible strain of *Neisseria gonorrhoeae*
   4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ceftriaxone

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GEPOTIDACIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Blujepa.

REFERENCES

Blujepa [Prescribing Information]. Durham, NC: GlaxoSmithKline; December 2025.

Created: 09/25
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GILTERITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GILTERITINIB FUMARATE	XOSPATA	45506		GPI-10 (2153302020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) (ICD-10 C92.02, C92.00) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GILTERITINIB (Xospata)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have a FMS-like tyrosine kinase 3 (FLT3: a type of gene) mutation (abnormal change), as detected by a Food and Drug Administration (FDA)-approved test

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xospata.

REFERENCES

Xospata [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; January 2022

Created: 03/19
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GIVINOSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GIVINOSTAT HYDROCHLORIDE	DUVYZAT	49667		GPI-10 (7460302520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   - The patient's diagnosis of DMD is confirmed by genetic testing
   - The patient has been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #12mL per day.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GIVINOSTAT (Duvyzat)** requires the following rule(s) be met for approval:
   A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   B. You are 6 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   D. Your diagnosis of DMD is confirmed by genetic testing
   E. You have been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GIVINOSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) **AND** meet the following criterion?
- The patient has been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently ambulatory **AND** meets the following criterion?
- The patient has shown improvement since starting Duvyzat, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time [Gower's maneuver], 10-meter [30 feet] run/walk time, North Star Ambulatory Assessment [NSAA])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #12mL per day.**
If no, continue to #3.

3. Is the patient currently non-ambulatory **AND** meets the following criterion?
- The patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength since starting Duvyzat, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #12mL per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GIVINOSTAT (Duvyzat)** requires the following rule(s) be met for renewal:
A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You have been on a stable dose of corticosteroids for at least 6 months AND will continue steroid therapy with Duvyzat
C. If you are currently ambulatory (can walk), approval also requires:
1. You have shown improvement since starting Duvyzat, as measured by a standard set of ambulatory or functional status measures (such as 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter [30 feet] run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])

(Renewal denial text continued on next page)

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GIVINOSTAT

RENEWAL CRITERIA (CONTINUED)

D. If you are currently non-ambulatory (cannot walk), approval also requires:

1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength since starting Duvyzat, as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Duvyzat.

REFERENCES

Duvyzat [Prescribing Information]. Concord, MA: ITF Therapeutics, LLC; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24

Created: 06/24
Client Approval: 06/24

P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GIVOSIRAN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GIVOSIRAN	GIVLAARI	46222		GPI-10 (8508002520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acute hepatic porphyria (AHP) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase- deficient porphyria [ADP/ALAD]) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has genetic confirmation of AHP mutation OR elevated (beyond reference range) urinary or plasma PBG (porphobilinogen) or ALA (aminolevulinic acid)
   - The patient has or is experiencing 4 or more recurrent attacks per year
   - The requested medication is prescribed by or given in consultation with a geneticist, hepatologist, hematologist, gastroenterologist, neurologist, dermatologist, or a healthcare provider experienced in managing AHP
   - Documentation of patient's current weight (to the nearest 0.1 kg)

   If yes, **approve for 6 months by HICL or GPI-10 at a dose of 2.5 mg/kg actual body weight as follows:**
   - **Weight ≤ 75.6 kg: #1mL (1 vial) per month.**
   - **Weight 75.7 kg to 151.2 kg: #2mL (2 vials) per month.**
   - **Weight 151.3 to 226.8 kg: #3mL (3 vials) per month (and so forth).**

   APPROVAL TEXT: Renewal requires: 1) patient has achieved or maintained clinical benefit compared to baseline, 2) patient has not received a liver transplant, and 3) documentation of patient's current weight.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GIVOSIRAN (Givlaari)** requires the following rule(s) be met for approval:
   A. You have acute hepatic porphyria (enzyme deficiency which leads to buildup of materials in the liver) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP/ALAD])
   B. You are 18 years of age or older
   C. You have genetic confirmation of AHP mutation (a change in your DNA that make up your gene), OR high (beyond reference range) urinary or plasma porphobilinogen (PBG), or aminolevulinic acid (ALA) (PBG and ALA: urine or blood tests that measure the level of porphyrins – a chemical that helps make hemoglobin in your body)
   (*Initial denial text continued on next page)*

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GIVOSIRAN (NSA)

INITIAL CRITERIA (CONTINUED)

D. You have or are experiencing 4 or more recurrent (continues to return) attacks per year
E. The medication is prescribed by or given in consultation with a geneticist (doctor who specializes in conditions of gene disorders), hepatologist (doctor who specializes in treating the liver), hematologist (doctor who specializes in the study of blood, blood-forming organs and blood diseases), gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), neurologist (doctor who specializes in disorders of the nervous system), dermatologist (doctor who treats conditions of the skin, hair and nails), or a healthcare provider experienced in managing acute hepatic porphyria
F. Your doctor provided documentation of your weight

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GIVOSIRAN (NSA)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acute hepatic porphyria (AHP) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase- deficient porphyria [ADP/ALAD]) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clinical benefit compared to baseline (e.g., less hemin use, less AHP attacks, improvement of AHP symptoms, etc.)
   - The patient has not received a liver transplant
   - Documentation of patient's current weight (to the nearest 0.1 kg)

   If yes, **approve for 12 months by HICL or GPI-10 at a dose of 2.5 mg/kg actual body weight as follows:**
   - **Weight ≤ 75.6 kg: #1mL (1 vial) per month.**
   - **Weight 75.7 kg to 151.2 kg: #2mL (2 vials) per month.**
   - **Weight 151.3 to 226.8 kg: #3mL (3 vials) per month (and so forth).**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GIVOSIRAN (Givlaari)** requires the following rule(s) be met for renewal:
   A. You have acute hepatic porphyria (AHP: enzyme deficiency which leads to buildup of materials in the liver) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP/ALAD])
   B. You have achieved or maintained clinical (medical) benefit compared to baseline (such as less hemin use, less AHP attacks, improvement of AHP symptoms, etc.)
   C. You have not received a liver transplant (replaced your bad liver with a healthy liver from another person)
   D. Your doctor provided documentation of your weight

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Givlaari.

REFERENCES

Givlaari [Prescribing Information]. San Diego, CA: PCI San Diego, Inc., September 2025.

Created: 02/20
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLASDEGIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLASDEGIB MALEATE	DAURISMO	45502		GPI-10 (2137003030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - The patient has newly-diagnosed AML
   - Daurismo will be used in combination with low-dose cytarabine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient has comorbidities that prevent use of intensive induction chemotherapy

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with a quantity limit as follows:**
   - **25mg: #2 per day.**
   - **100mg: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLASDEGIB (Daurismo)** requires the following rule(s) be met for approval:
   A. You have newly-diagnosed acute myeloid leukemia (AML: a type of blood and bone marrow cancer)
   B. Daurismo will be used in combination with low-dose cytarabine
   C. You are 75 years of age or older, OR you have comorbidities (more than one disease) that prevents the use of intensive induction chemotherapy (start of high dose cancer treatment)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLASDEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daurismo.

REFERENCES

Daurismo [Prescribing Information]. New York, NY: Pfizer Inc.; March 2023.

Created: 01/19
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLATIRAMER ACETATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLATIRAMER ACETATE	COPAXONE, GLATOPA, GLATIRAMER ACETATE	12810		GPI-10 (6240003010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **20mg/mL: #1mL per day.**
   - **40mg/mL: #12mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLATIRAMER ACETATE (Copaxone, Glatopa)** requires the following rule(s) be met for approval:
   1. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   2. You are 18 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Copaxone and Glatopa.

REFERENCES

Copaxone [Prescribing Information]. Overland Park, KS: Teva; January 2025.
Glatopa [Prescribing Information]. Princeton, NJ: Sandoz Inc.; December 2023.

Created: 02/14
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 02/14

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLECAPREVIR/PIBRENTASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLECAPREVIR/ PIBRENTASVIR	MAVYRET	44453		GPI-10 (1235990235)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute hepatitis C virus (HCV) (ICD-10 B17.1) and meet **ALL** of the following criteria?
   - The patient is 3 years of age or older
   - The patient has genotype 1, 2, 3, 4, 5, or 6 infection

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient have an HCV RNA level within the past 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
   - The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
   - The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C)
   - Mavyret will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., rifampin, atazanavir, carbamazepine, phenytoin, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin at doses greater than 10mg, cyclosporine at doses greater than 100mg/day, medications containing more than 20mcg of ethinyl estradiol, St. John's wort)
   - Mavyret will be used concurrently with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 weeks by GPID or GPI-14 for all strengths as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
- The patient is 3 years of age or older
- The patient has genotype 1, 2, 3, 4, 5, or 6 infection

If yes, continue to #5.
If no, continue to #17.

5. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #6.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ANY** of the following criteria?
- The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C)
- Mavyret will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., rifampin, atazanavir, carbamazepine, phenytoin, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin at doses greater than 10mg, cyclosporine at doses greater than 100mg/day, medications containing more than 20mcg of ethinyl estradiol, St. John's wort)
- Mavyret will be used concurrently with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #7.

7. Is the patient treatment-naïve?

If yes, continue to #8.
If no, continue to #10.

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GUIDELINES FOR USE (CONTINUED)

8. Does the patient have compensated cirrhosis (Child-Pugh A) or does not have cirrhosis?

   If yes, **approve for 8 weeks by GPID or GPI-14 for all strengths as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, continue to #9.

9. Is the patient post-liver or post-kidney transplant?

   If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths as follows:**
   - **100mg-40mg tablet: #3 per day.**
   - **50mg-20mg pellets: #5 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

10. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    - The patient is less than 18 years of age
    - The patient is interferon-experienced

    If yes, **approve for 8 weeks by GPID or GPI-14 for all strengths as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no continue to #11.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

11. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    - The patient has genotype 1 OR genotype 2, 3, 4, 5, or 6 and is less than 18 years of age
    - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
    - The patient has prior treatment experience with an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])
    - The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [grazoprevir/elbasvir])

    If yes, **approve for 16 weeks by GPID or GPI-14 for all strengths as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #12.

12. Is the patient treatment-experienced and meets **ONE** of the following criteria?
    - The patient has failed prior treatment with a sofosbuvir-based regimen with no NS3/4A protease inhibitor (e.g., Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir], Sovaldi [sofosbuvir])
    - The patient has previously failed Mavyret AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
    - The patient has previously failed Vosevi (sofosbuvir/velpatasvir/voxilaprevir) AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
    - The patient is less than 18 years of age, has genotype 3, AND is interferon-experienced

    If yes, **approve for 16 weeks by GPID or GPI-14 for all strengths as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #13.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

13. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    - The patient has genotype 1, 2, 4, 5, or 6
    - The patient does not have cirrhosis
    - The patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)
    - The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 8 weeks by GPID or GPI-14 for all strengths as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #14.

14. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    - The patient has genotype 1, 2, 4, 5, or 6
    - The patient has compensated cirrhosis (Child-Pugh A)
    - The patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)
    - The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 12 weeks for by GPID or GPI-14 for all strengths as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #15.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

15. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    - The patient has genotype 1 OR genotype 2, 3, 4, 5, or 6 and is less than 18 years of age
    - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
    - The patient has prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir])
    - The patient has NO prior treatment experience with an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #16.

16. Is the patient treatment-experienced and meets **ALL** of the following criteria?
    - The patient has genotype 3
    - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
    - The patient has prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)
    - The patient has NO prior treatment experience with an NS3/4A protease inhibitor (e.g., Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

    If yes, **approve for 16 weeks by GPID or GPI-14 for all strengths as follows:**
    - **100mg-40mg tablet: #3 per day.**
    - **50mg-20mg pellets: #5 per day.**

    If no, continue to #17.

17. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires the following rule(s) be met for approval:

A. You have acute (short-term) or chronic (long-term) hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 3 years of age or older
C. You have a genotype 1, 2, 3, 4, 5, or 6 infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in your blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
G. You will NOT use Mavyret concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as rifampin, atazanavir, carbamazepine, phenytoin, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin at doses greater than 10mg, cyclosporine at doses greater than 100mg/day, medications containing more than 20mcg of ethinyl estradiol, St. John's wort)
H. You will NOT use Mavyret concurrently (at the same time) with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
I. If you have chronic hepatitis C virus and are treatment naive (no prior treatment), approval also requires ALL of the following:
    1. You meet ONE of the following:
        a. You do not have cirrhosis (liver damage or scarring)
        b. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
        c. You received a liver transplant (replaced your liver)
        d. You received a kidney transplant (replaced your kidney)

(Denial text continued on next page)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

J. If you have chronic hepatitis C virus, are treatment-experienced (failed prior treatment) and prior therapy did not contain an NS5A inhibitor, approval also requires ONE of the following:

1. You have a genotype 1, 2, 4, 5, or 6 infection, and you have compensated cirrhosis (a condition where there is liver damage and scarring without major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) or you do not have cirrhosis (liver damage and scarring), and you have prior treatment experience with regimens containing interferon/peginterferon, ribavirin and/or Sovaldi (sofosbuvir), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])
2. You have genotype 1 OR genotype 2, 3, 4, 5, or 6 and are less than 18 years of age, and you have compensated cirrhosis (Child-Pugh A) OR you do not have cirrhosis, and you have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]), and you do not have prior treatment experience with an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])
3. You have a genotype 3 infection, and you have compensated cirrhosis (Child-Pugh A) OR you do not have cirrhosis, and you have prior treatment experience with regimens containing interferon/peginterferon, ribavirin, and/or Sovaldi (sofosbuvir), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir]) or an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir])

(Denial text continued on next page)

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GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

K. If you have chronic hepatitis C virus and are treatment-experienced (failed prior treatment), approval also requires ALL of the following:

1. You meet ONE of the following:
   a. You are less than 18 years of age AND had prior treatment with an interferon
   b. You have genotype 1 OR genotype 2, 3, 4, 5, or 6 and are less than 18 years of age, and you have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring), and you have prior treatment experience with an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Epclusa [velpatasvir/sofosbuvir]), and you do not have prior treatment experience with an NS3/4A protease inhibitor (such as Olysio [simeprevir], Zepatier [elbasvir/grazoprevir])
   c. You have failed prior treatment with a sofosbuvir-based regimen with no NS3/4A protease inhibitor (such as Epclusa [velpatasvir/sofosbuvir], Harvoni [ledipasvir/sofosbuvir], Sovaldi [sofosbuvir])
   d. You have failed Mavyret AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
   e. You have failed Vosevi (sofosbuvir/velpatasvir/voxilaprevir) AND Mavyret will be used with Sovaldi (sofosbuvir) and ribavirin
   f. You are less than 18 years of age, have genotype 3, AND you had prior treatment with an interferon

L. Mavyret will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavyret.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed October 2023.

Mavyret [Prescribing Information]. North Chicago, IL: Abbvie; June 2025.

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GLOFITAMAB-GXBM (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLOFITAMAB-GXBM	COLUMVI	49012		GPI-10 (2135203500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS), OR large B-cell lymphoma (LBCL) arising from follicular lymphoma, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient previously received at least two lines of systemic therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
   - The patient will receive or has received a single dose of Gazyva (obinutuzumab) as a pretreatment prior to initiating Columvi
   - The patient has NOT previously received more than 12 cycles of Columvi

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.43 mL per day for 12 fills.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLOFITAMAB-GXBM (Columvi)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory diffuse large B-cell lymphoma (DLBCL: a type of white blood cell cancer that has returned or is not responding to treatment), not otherwise specified (NOS), or large B-cell lymphoma (LBCL) arising from follicular lymphoma (a type of blood cancer)
   B. You are 18 years of age or older
   C. You previously received at least two lines of systemic therapy (treatment that travels throughout the body) (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], GemOx [gemcitabine, oxaliplatin])
   D. You will receive or have received a single dose of Gazyva (obinutuzumab) as a pretreatment prior to initiating Columvi
   E. You have NOT previously received more than 12 cycles of Columvi

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLOFITAMAB-GXBM (NSA)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Columvi.

REFERENCES
Columvi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 07/23
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P&T Approval: 07/23

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GLP-1 AGONIST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EXENATIDE MICROSPHERES	BYDUREON BCISE	38451		GPI-10 (2717002000)	
EXENATIDE	BYETTA, EXENATIDE	32893			
TIRZEPATIDE	MOUNJARO	48014		GPI-10 (2717308000)	BRAND ≠ ZEPBOUND
SEMAGLUTIDE	OZEMPIC, RYBELSUS	44675		GPI-10 (2717007000)	BRAND ≠ WEGOVY
DULAGLUTIDE	TRULICITY	41421		GPI-10 (2717001500)	
LIRAGLUTIDE	VICTOZA, LIRAGLUTIDE		26189	GPI-10 (2717005000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 2 diabetes (ICD-10 Groups E08, E09, E13, E11 except ICD-10 E11.A)?

   If yes, **approve the requested agent for 12 months as follows:**
   - **Bydureon BCise: Approve by HICL or GPI-10.**
   - **Byetta (exenatide): Approve by HICL or GPI-10.**
   - **Mounjaro: Approve all strengths by GPID or GPI-14.**
   - **Ozempic: Approve all strengths by GPID or GPI-14.**
   - **Rybelsus: Approve all strengths by GPID or GPI-14.**
   - **Trulicity: Approve by HICL or GPI-10.**
   - **Victoza (liraglutide): Approve all strengths by GPID or GPI-14.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLP-1 AGONIST (Bydureon BCise, Byetta [exenatide], Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza [liraglutide])** requires the following rule(s) be met for approval:
   A. You have type 2 diabetes (a disorder with high blood sugar)

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GLP-1 AGONIST

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, or Victoza.

REFERENCES

Bydureon BCise [Prescribing Information]. Wilmington, DE: AstraZeneca Pharma.; May 2025.
Byetta [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals, LP; September 2025.
Exenatide [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; November 2024.
Mounjaro [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; December 2025.
Ozempic [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; October 2025.
Rybelsus [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; January 2026.
Trulicity [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; May 2025.
Victoza [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; October 2025.

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GLYCEROL PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLYCEROL PHENYLBUTYRATE	RAVICTI, GLYCEROL PHENYLBUTYRATE	39990		GPI-10 (3090803000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 Group E72.2) and meet **ALL** of the following criteria?
   - The patient's disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
   - The patient's UCD is confirmed by enzymatic, biochemical, or genetic testing
   - The requested medication will be used as adjunctive therapy along with dietary protein restriction
   - The patient does NOT have N-acetylglutamate synthetase (NAGS) deficiency or acute hyperammonemia
   - The patient had a trial of or contraindication to Buphenyl (sodium phenylbutyrate)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #17.5mL per day.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for approval:
   A. You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
   B. Your disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
   C. Your disorder is confirmed by enzymatic, biochemical, or genetic testing (types of lab tests)
   D. The requested medication will be used as adjunctive (add-on) therapy along with dietary protein restriction
   E. You do NOT have a deficiency (low level) of N-acetylglutamate synthetase (NAGS: a type of enzyme) or acute hyperammonemia (sudden and short-term increase in ammonia levels to a critical level)
   F. You have tried or have a contraindication to (harmful for you to use) Buphenyl (sodium phenylbutyrate)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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GLYCEROL PHENYLBUTYRATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 Group E72.2) **AND** meet the following criterion?
   - The patient had a clinical benefit compared to baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #17.5mL per day.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for renewal:
   A. You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
   B. You had a clinical benefit compared to baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ravicti.

REFERENCES

Ravicti [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc; September 2021.

Created: 02/13
Effective: 11/03/25 Client Approval: 10/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GLYCOPYRRONIUM TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLYCOPYRRONIUM TOSYLATE	QBREXZA	45086		GPI-10 (9097003020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary axillary hyperhidrosis (ICD-10 L74.510) and meet **ALL** of the following criteria?
- The patient is 9 years of age or older
- Qbrexza will NOT be used concurrently with other topical anticholinergics indicated for primary axillary hyperhidrosis (e.g., Sofdra [sofpironium bromide])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 packet per day.** If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** requires the following rule(s) be met for approval:
A. You have primary axillary hyperhidrosis (excessive underarm sweating)
B. You are 9 years of age or older
C. You will NOT use Qbrexza concurrently (at the same time) with other topical anticholinergics indicated for primary axillary hyperhidrosis (such as Sofdra [sofpironium bromide])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qbrexza.

REFERENCES

Qbrexza [Prescribing Information]. Scottsdale, AZ: Journey Medical Corporation; October 2022.

Created: 11/18
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLIMUMAB	SIMPONI ARIA		34983	GPI-14 (66270040002015)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is concurrently using or has a contraindication to methotrexate
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a ONE conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

     If yes, continue to #2.
     If no, continue to #3.

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
     - **FIRST APPROVAL: Approve for 1 month with a total fill count of 1. (PAC NOTE: Enter a Min Day Supply of 28 days).**
     - **SECOND APPROVAL: Approve for 5 months for 1 fill per 56 days. (total fill count = 3; start date is 2 days before the end of the first approval) (PAC NOTE: Enter a Min Day Supply of 56 days).**

     If no, do not approve.
     DENIAL TEXT: See initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

     If yes, continue to #4.
     If no, continue to #6.

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 5 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Xeljanz IR (tofacitinib IR)
     - Rinvoq (upadacitinib)

     [**NOTE:** Xeljanz and Rinvoq require additional criteria of inadequate response or intolerance to a TNF blocker (e.g., Enbrel)]
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Enbrel (etanercept)
     - Otezla (apremilast)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Xeljanz IR (tofacitinib IR)
     - Rinvoq (upadacitinib)

     [**NOTE:** Xeljanz and Rinvoq require additional criteria of inadequate response or intolerance to a TNF blocker (e.g., Enbrel)]
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14. Enter two authorizations as follows:**
     - **FIRST APPROVAL: Approve for 1 month for 1 fill count. (Enter Min Day Supply of 28 days).**
     - **SECOND APPROVAL: Approve for 5 months for 1 fill per 56 days. (fill count = 3; start date is 2 days before the end of the first approval) (Enter Min Day Supply of 56 days).**

     If no, continue to #5.

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

5. Is the patient 18 years of age or older **AND** meets the following criterion?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - o Enbrel (etanercept)
     - o Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - o Otezla (apremilast)
     - o Tremfya (guselkumab)
     - o Skyrizi (risankizumab-rzaa)
     - o Taltz (ixekizumab)
     - o Bimzelx (bimekizumab-bkzx)
     - o Sotyktu (deucravacitinib)
     - o Adalimumab-ryvk/adalimumab-aaty
     - o Xeljanz (tofacitinib IR or XR)
     - o Rinvoq (upadacitinib)

     [**NOTE:** Xeljanz and Rinvoq require additional criteria of inadequate response or intolerance to a TNF blocker (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel)]
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14. Enter two authorizations as follows:**
     - **FIRST APPROVAL: Approve for 1 month for 1 fill count. (Enter Min Day Supply of 28 days).**
     - **SECOND APPROVAL: Approve for 5 months for 1 fill per 56 days. (fill count = 3; start date is 2 days before the end of the first approval) (Enter Min Day Supply of 56 days).**

     If no, do not approve.
     DENIAL TEXT: See initial denial text at the end of the guideline.

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a total fill count of 1. (PAC NOTE: Enter a Min Day Supply of 28 days).**
   - **SECOND APPROVAL: Approve for 5 months for 1 fill per 56 days. (total fill count = 3; start date is 2 days before the end of the first approval) (PAC NOTE: Enter a Min Day Supply of 56 days).**

   If no, continue to #7.

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a total fill count of 1. (PAC NOTE: Enter a Min Day Supply of 28 days).**
   - **SECOND APPROVAL: Approve for 5 months for 1 fill per 56 days. (total fill count = 3; start date is 2 days before the end of the first approval) (PAC NOTE: Enter a Min Day Supply of 56 days).**

   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
4. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. If you have psoriatic arthritis, approval also requires:
1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Enbrel (etanercept)
      iii. Otezla (apremilast)
      iv. Tremfya (guselkumab)
      v. Skyrizi (risankizumab-rzaa)
      vi. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      vii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      iii. Otezla (apremilast)
      iv. Tremfya (guselkumab)
      v. Skyrizi (risankizumab-rzaa)
      vi. Taltz (ixekizumab)
      vii. Bimzelx (bimekizumab-bkzx)
      viii. Sotyktu (deucravacitinib)
      ix. Adalimumab-ryvk/adalimumab-aaty
      x. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      xi. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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GOLIMUMAB - IV

INITIAL CRITERIA (CONTINUED)

E. If you have polyarticular juvenile idiopathic arthritis, approval also requires:

1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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GOLIMUMAB - IV

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient is concurrently using or has a contraindication to methotrexate
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for 1 fill per 56 days (total fill count = 6) (PAC NOTE: Enter a Min Day Supply of 56 days).**

   If no, do not approve.
   DENIAL TEXT: See renewal denial text at the end of the guideline.

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GOLIMUMAB - IV

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
- Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, continue to #4.
If no, continue to #5.

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GOLIMUMAB - IV

RENEWAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 5 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Xeljanz IR (tofacitinib IR)
     - Rinvoq (upadacitinib)

     [**NOTE:** Xeljanz and Rinvoq require additional criteria of inadequate response or intolerance to a TNF blocker (e.g., Enbrel)]
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Enbrel (etanercept)
     - Otezla (apremilast)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Xeljanz IR (tofacitinib IR)
     - Rinvoq (upadacitinib)

     [**NOTE:** Xeljanz and Rinvoq require additional criteria of inadequate response or intolerance to a TNF blocker (e.g., Enbrel)]
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Otezla (apremilast)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Sotyktu (deucravacitinib)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR)
     - Rinvoq (upadacitinib)

     [**NOTE:** Xeljanz and Rinvoq require additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel)]
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for 1 fill per 56 days (total fill count = 6) (PAC NOTE: Enter a Min Day Supply of 56 days).**

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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GOLIMUMAB - IV

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for 1 fill per 56 days (total fill count = 6) (PAC NOTE: Enter a Min Day Supply of 56 days).**

   If no, continue to #6.

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GOLIMUMAB - IV

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - Simponi Aria will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for 1 fill per 56 days (total fill count = 6) (PAC NOTE: Enter a Min Day Supply of 56 days).**

   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **GOLIMUMAB - IV (Simponi Aria)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)

   B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
      2. You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

3. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
4. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. If you have psoriatic arthritis, renewal also requires:

1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
3. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

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RENEWAL CRITERIA (CONTINUED)

b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   ii. Enbrel (etanercept)
   iii. Otezla (apremilast)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Xeljanz IR (tofacitinib immediate-release) (NOTE: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   vii. Rinvoq (upadacitinib) (NOTE: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   i. Enbrel (etanercept)
   ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   iii. Otezla (apremilast)
   iv. Tremfya (guselkumab)
   v. Skyrizi (risankizumab-rzaa)
   vi. Taltz (ixekizumab)
   vii. Bimzelx (bimekizumab-bkzx)
   viii. Sotyktu (deucravacitinib)
   ix. Adalimumab-ryvk/adalimumab-aaty
   x. Xeljanz (tofacitinib immediate-release or extended-release) (NOTE: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   xi. Rinvoq (upadacitinib) (NOTE: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

D. If you have ankylosing spondylitis, renewal also requires:

1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

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RENEWAL CRITERIA (CONTINUED)

3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:

1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Simponi Aria concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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GOLIMUMAB - IV

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Simponi Aria.

REFERENCES
Simponi Aria [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; April 2025.

Created: 11/13
Effective: 07/15/26 Client Approval: 07/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLIMUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLIMUMAB	SIMPONI		22533 22536 34697 35001	GPI-14 (6627004000D540, 6627004000E540, 6627004000D520, 6627004000E520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is concurrently using or has a contraindication to methotrexate
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve all formulations of the 50mg/0.5mL strength for 6 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve all formulations of the 50mg/0.5mL strength for 6 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 50mg/0.5mL strength for 6 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient weighs at least 15 kg (33 lbs)
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient is less than 5 years of age
   - The patient is 5 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to ONE of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve all formulations and strengths for 1 month as follows:**
     - **100mg/mL: #3 mL per 28 days.**
     - **50mg/0.5mL: #1.5 mL per 28 days.**
   - **SECOND APPROVAL: Approve all formulations of the requested strength for 5 months as follows (please enter a start date of 1 week AFTER the end date of the first approval):**
     - **100mg/mL: #1 mL per 28 days.**
     - **50mg/0.5mL: #0.5 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
4. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

D. If you have moderate to severe ankylosing spondylitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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GOLIMUMAB - SQ

INITIAL CRITERIA (CONTINUED)

E. If you have moderate to severe ulcerative colitis, approval also requires:

1. You weigh at least 15 kilograms (33 pounds)
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
4. You meet ONE of the following:
   a. You are less than 5 years of age
   b. You are 5 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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GOLIMUMAB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient is concurrently using or has a contraindication to methotrexate
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 50mg/0.5mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
- Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve all formulations of the 50mg/0.5mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

If no, continue to #4.

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 50mg/0.5mL strength for 12 months by GPID or GPI-14 with a quantity limit of #0.5 mL per 28 days.**

   If no, continue to #5.

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Simponi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient is less than 5 years of age
   - The patient is 5 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to ONE of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   - **100mg/mL: #1 mL per 28 days.**
   - **50mg/0.5mL: #0.5 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GOLIMUMAB-SQ (Simponi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You are concurrently (at the same time) using or have a contraindication to (harmful for you to use) methotrexate
   3. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, renewal also requires:

1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

D. If you have moderate to severe ankylosing spondylitis, renewal also requires:

1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) score while on therapy
2. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

E. If you have moderate to severe ulcerative colitis, renewal also requires:

1. You will NOT use Simponi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
2. You meet ONE of the following:
   a. You are less than 5 years of age
   b. You are 5 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Simponi.

REFERENCES

Simponi [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; October 2025.

Created: 06/09
Effective: 09/09/26 Client Approval: 09/26 DMC Approval: 09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLODIRSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOLODIRSEN	VYONDYS-53	46254		GPI-10 (7460004200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   - The patient has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping therapy
   - Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of DMD at a DMD treatment center
   - The patient is ambulatory
   - The patient is currently receiving treatment with or has a contraindication to corticosteroids (e.g., prednisone, prednisolone)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLODIRSEN (Vyondys 53)** requires the following rule(s) be met for approval:
   A. You have Duchenne muscular dystrophy (DMD: a type of inherited muscle disorder)
   B. You have a confirmed mutation (abnormal change in a type of gene) in the DMD gene that will respond to exon 53 skipping therapy (a type of therapy to treat DMD)
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) specializing in the treatment of DMD at a DMD treatment center
   D. You are ambulatory (able to walk)
   E. You are currently receiving treatment with or you have a contraindication to (harmful for you to use) corticosteroids (such as prednisone, prednisolone)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOLODIRSEN

RENEWAL CRITERIA

1. Does the patient meet **ONE** of the following criteria?
   - The patient has maintained or demonstrated a less than expected decline in ambulatory ability based on muscle function assessments (e.g., 6-minute walk test)
   - The patient has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GOLODIRSEN (Vyondys 53)** requires ONE of the following rule(s) be met for renewal:
   A. You have maintained or demonstrated a less than expected decline in ambulatory ability (ability to walk) based on muscle function assessments (such as the 6-minute walk test)
   B. You have maintained or demonstrated a less than expected decline in other muscle function (pulmonary [lung] or cardiac [heart] function)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyondys 53.

REFERENCES

Vyondys 53 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc.; June 2024.

Created: 02/20
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GOSERELIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GOSERELIN ACETATE	ZOLADEX	21114		GPI-10 (2140500510)	

GUIDELINES FOR USE

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient have a diagnosis of locally confined carcinoma of the prostate (ICD-10 C61) **AND** meet the following criterion?
   - Zoladex will be used in combination with Eulexin (flutamide)

   If yes, **approve for 4 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **3.6 mg: #1 per 4 weeks.**
   - **10.8 mg: #1 (one time fill).**

   If no, continue to #3.

3. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **3.6 mg: #1 per 4 weeks.**
   - **10.8 mg: #1 per 12 weeks.**

   If no, continue to #4.

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GOSERELIN

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe pain from endometriosis (ICD-10 Groups N80 and R52) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The patient had a trial of or contraindication to the clinical standard of care agents: a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   - Zoladex will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa [elagolix], Myfembree [relugolix-estradiol-norethindrone], Lupron Depot [leuprolide])
   - The patient has NOT received more than 6 months of treatment with Zoladex per lifetime

   If yes, **approve 3.6 mg for 6 months by GPID or GPI-14 with a quantity limit of #1 per 4 weeks.**

   If no, continue to #5.

5. Does the patient have a diagnosis of dysfunctional uterine bleeding (ICD-10 N93.8) **AND** meet the following criterion?
   - Zoladex will be used as an endometrial-thinning agent prior to endometrial ablation

   If yes, **approve 3.6 mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per 4 weeks.**

   If no, continue to #6.

6. Does the patient have a diagnosis of advanced breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient is a premenopausal or perimenopausal female

   If yes, **approve 3.6 mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per 4 weeks.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GOSERELIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GOSERELIN (Zoladex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Locally confined carcinoma (cancer) of the prostate
   3. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
   4. Moderate to severe pain from endometriosis (condition affecting the uterus)
   5. Dysfunctional uterine bleeding (abnormal uterine bleeding)
   6. Advanced breast cancer (breast cancer that has spread to nearby tissue or organs)

B. If you have gender dysphoria, approval also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. If you have locally confined carcinoma of the prostate, approval also requires:
   1. Zoladex will be used in combination with Eulexin (flutamide)

D. If you have moderate to severe pain from endometriosis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   3. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medications: a nonsteroidal anti-inflammatory drug (NSAID: such as ibuprofen, meloxicam, naproxen) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   4. You will NOT use Zoladex concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa [elagolix], Myfembree [relugolix-estradiol-norethindrone], Lupron Depot [leuprolide])
   5. You have NOT received more than 6 months of treatment with Zoladex per lifetime

E. If you have dysfunctional uterine bleeding, approval also requires:
   1. Zoladex will be used as an endometrial-thinning agent prior to endometrial ablation (a type of surgical procedure)

F. If you have advanced breast cancer, approval also requires:
   1. You are a premenopausal (before menopause) or perimenopausal (time around menopause) female

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GOSERELIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoladex.

REFERENCES

Zoladex [Prescribing Information]. Deerfield, IL: TerSera Therapeutics LLC; September 2025.

Created: 03/18
Effective: 08/07/26 Client Approval: 08/26 DMC Approval: 08/04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

GUSELKUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GUSELKUMAB	TREMFYA	44418		GPI-10 (5250402500, 9025054200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Tremfya
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

   If yes, **approve all formulations of the 100mg/mL strength for a total of 6 months. Please enter TWO approvals by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 56 days (please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 6 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, **approve all formulations of the 100mg/mL strength for a total of 6 months. Please enter TWO approvals by GPID or GPI-14 as follows:**
- **FIRST APPROVAL: Approve for 1 month with a quantity limit of #1mL per 28 days.**
- **SECOND APPROVAL: Approve for 5 months with a quantity limit of #1mL per 56 days (please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a gastroenterologist
- Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
- **FIRST APPROVAL: Approve the requested formulation for 2 months with the following quantity limits:**
  - **200mg/20mL vial: #20mL per 28 days.**
  - **200mg/2mL pen/syringe: #4mL per 28 days.**
- **SECOND APPROVAL: Approve all formulations of the requested strength for 4 months with the following quantity limits (please enter a start date of 3 WEEKS AFTER the END date of the first approval):**
  - **100mg/mL: #1mL per 56 days.**
  - **200mg/2mL: #2mL per 28 days.**

If no, continue to #6.

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for a total of 6 months by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve the requested formulation for 2 months with the following quantity limits:**
     - **200mg/20mL vial: #20mL per 28 days.**
     - **200mg/2mL pen/syringe: #4mL per 28 days.**
   - **SECOND APPROVAL: Approve all formulations of the requested strength for 4 months with the following quantity limits (please enter a start date of 3 WEEKS AFTER the END date of the first approval):**
     - **100mg/mL: #1mL per 56 days.**
     - **200mg/2mL: #2mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
      4. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe plaque psoriasis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type skin condition)
4. You meet ONE of the following:
   a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis (a type of skin condition)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
5. You meet ONE of the following:
   a. You were previously stable on another biologic and are switching to Tremfya
   b. You have psoriasis covering 3 percent or more of body surface area (BSA)
   c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

C. If you have psoriatic arthritis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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GUSELKUMAB

INITIAL CRITERIA (CONTINUED)

E. If you have moderate to severe Crohn's disease, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

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GUSELKUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve all formulations of the 100mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender or swollen joint count while on therapy
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 100mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 56 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100mg/mL: #1mL per 56 days.**
   - **200mg/2mL: #2mL per 28 days.**

   If no, continue to #4.

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GUSELKUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Tremfya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100mg/mL: #1mL per 56 days.**
   - **200mg/2mL: #2mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
      4. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

   B. If you have moderate to severe plaque psoriasis, renewal also requires:
      1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
      2. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

   C. If you have psoriatic arthritis, renewal also requires:
      1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      2. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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GUSELKUMAB

RENEWAL CRITERIA (CONTINUED)

D. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

E. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use Tremfya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tremfya.

REFERENCES
Tremfya [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; September 2025.

Created: 07/17
Effective: 06/17/26 Client Approval: 06/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HIGH CONCENTRATION OPIOID ORAL SOLUTIONS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MORPHINE SULFATE	MORPHINE SULFATE		16063	GPI-14 (65100055102090)	
OXYCODONE HCL	OXYCODONE HCL		16281	GPI-14 (65100075101320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following?
   - The patient is enrolled in hospice
   - The patient is receiving palliative care or end-of-life care

   If yes, **approve the requested drug for a lifetime approval by GPID or GPI-14.**
   If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?
   - The patient has previous use of at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid
   - The patient has trouble swallowing opioid tablets, capsules, or large volumes of liquid

   If yes, **approve the requested drug for 3 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HIGH CONCENTRATION OPIOID ORAL SOLUTIONS (morphine sulfate, oxycodone hydrochloride)** requires the following rule(s) be met for approval:
   A. You have pain severe enough to require opioid analgesic and for which alternative treatments are inadequate
   (Denial text continued on next page)

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HIGH CONCENTRATION OPIOID ORAL SOLUTIONS

GUIDELINES FOR USE (CONTINUED)

B. You meet ONE of the following:
   1. You are enrolled in hospice OR you are receiving palliative care or end-of-life care
   2. You meet ALL of the following:
      a. You have previous use of at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid
      b. You have trouble swallowing opioid tablets, capsules, or large volumes of liquid

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Morphine Sulfate or Oxycodone Hydrochloride oral solution.

REFERENCES

Morphine Sulfate [Prescribing Information]. Baudette, MN: ANI Pharmaceuticals Inc., April 2021
Oxycodone Hydrochloride [Prescribing Information]. East Windsor, NJ: Aurobindo Pharma USA, Inc., February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 07/21
Client Approval: 08/21
P&T Approval: 04/21

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HISTRELIN-SUPPRELIN LA (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HISTRELIN ACETATE	SUPPRELIN LA	21104		GPI-10 (3008004510)	BRAND = SUPPRELIN LA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - There is documentation of pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by NDC with a quantity limit of #1 per 12 months.**
   If no, continue to #3.

3. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - There is documentation of pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by NDC with a quantity limit of #1 per 12 months.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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HISTRELIN-SUPPRELIN LA (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HISTRELIN-SUPPRELIN LA** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)

B. If you are female and have central precocious puberty, approval also requires:
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH: a type of hormone) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 8 years of age when your condition started
   5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

C. If you are male and have central precocious puberty, approval also requires:
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH: a type of hormone) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH: a type of hormone) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 9 years of age when your condition started
   5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HISTRELIN-SUPPRELIN LA (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnosis of gender dysphoria, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of central precocious puberty (CPP) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has not reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months by NDC with a quantity limit of #1 per 12 months.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HISTRELIN-SUPPRELIN LA** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in girls and boys)
   B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have not reached the actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Supprelin LA.

REFERENCES

Supprelin LA [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals; April 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 03/18
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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HISTRELIN-VANTAS (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HISTRELIN ACETATE	VANTAS	21104		GPI-10 (2140500710)	BRAND = VANTAS

GUIDELINES FOR USE

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer?

   If yes, **approve for 12 months by NDC with a quantity limit of #1 per 12 months.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HISTRELIN-VANTAS** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vantas.

REFERENCES

Vantas [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals Inc.; February 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 03/18
Client Approval: 01/23
P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYALURONATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYALURONATE SODIUM	EUFLEXXA, HYALGAN, GEL-ONE, GELSYN-3, ORTHOVISC, SUPARTZ FX, SYNOJOYNT, GENVISC 850, VISCO-3, TRIVISC, TRILURON, SODIUM HYALURONATE		21448 32121 32122 41795	GPI-10 (7580006000) (7580002000) (7580007010)	
HYALURONATE SODIUM, STABILIZED	MONOVISC, DUROLANE		36397 33139		
HYALURONATE, MODIFIED, NON-CROSSLINK, HYALURONAN	HYMOVIS, HYMOVIS ONE	42225			
HYLAN G-F 20	SYNVISC, SYNVISC-ONE	26552		GPI-10 (7580004000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of osteoarthritis of the knee (ICD-10 Group M17) and meet **ALL** of the following criteria?
- The patient is 21 years of age or older
- The patient has failed a 6-week trial of non-pharmacologic therapy (e.g., education, exercise, use of insoles or braces, weight reduction, physical therapy)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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HYALURONATE

INITIAL CRITERIA (CONTINUED)

2. Is the request for Euflexxa, Synvisc, or Synvisc-One and the patient meets **ONE** of the following criteria?
   - The patient had a trial of or contraindication to an intra-articular steroid (e.g., methylprednisolone acetate, triamcinolone acetonide)
   - The patient had a trial of or contraindication to a topical NSAID (e.g., diclofenac)
   - The patient had a trial of or contraindication to an oral NSAID (e.g., meloxicam, diclofenac)
   - The patient had a trial of or contraindication to acetaminophen

   If yes, **approve the requested medication for 6 months as follows:**
   - **Euflexxa: Approve by NDC.**
   - **Synvisc, Synvisc-One: Approve by HICL or GPI-10.**

   If no, continue to #3.

3. Is the request for Durolane, Gel-One, Gelsyn-3, Genvisc 850, Hyalgan, Hymovis, Hymovis One, Monovisc, Orthovisc, Supartz FX, Triluron, Trivisc, Visco-3, Synojoynt, or Sodium Hyaluronate **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to Euflexxa AND Synvisc or Synvisc-One

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to an intra-articular steroid (e.g., methylprednisolone acetate, triamcinolone acetonide)
   - The patient had a trial of or contraindication to a topical NSAID (e.g., diclofenac)
   - The patient had a trial of or contraindication to an oral NSAID (e.g., meloxicam, diclofenac)
   - The patient had a trial of or contraindication to acetaminophen

   If yes, **approve for 6 months by HICL or GPI-10.**If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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HYALURONATE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HYALURONATE (Euflexxa, Gel-One, Gelsyn-3, Hyalgan, Hymovis, Hymovis One, Monovisc, Orthovisc, Supartz FX, Synojoynt, Synvisc, Synvisc-One, Genvisc 850, Visco-3, Trivisc, Durolane, Triluron, Sodium Hyaluronate)** requires the following rule(s) be met for approval:

A. You have osteoarthritis (a type of joint condition) of the knee
B. You are 21 years of age or older
C. You have failed a 6-week trial of non-pharmacologic (non-drug) therapy (such as education, exercise, use of insoles or braces, weight loss, physical therapy [exercises to restore health])
D. If the request is for Euflexxa, Synvisc, or Synvisc-One, approval also requires ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) an intra-articular (injected within the joint) steroid (such as methylprednisolone acetate, triamcinolone acetonide)
    2. You have tried or have a contraindication to (harmful for you to use) a topical non- steroidal anti-inflammatory drug (NSAID) (such as diclofenac)
    3. You have tried or have a contraindication to (harmful for you to use) an oral non- steroidal anti-inflammatory drug (NSAID) (such as meloxicam, diclofenac)
    4. You have tried or have a contraindication to (harmful for you to use) acetaminophen
E. If the request is for Durolane, Gel-One, Gelsyn-3, Genvisc 850, Hyalgan, Hymovis, Hymovis One, Monovisc, Orthovisc, Supartz FX, Triluron, Trivisc, Visco-3, Synojoynt, or Sodium Hyaluronate, approval also requires:
    1. You have tried or have a contraindication to (harmful for you to use) Euflexxa AND Synvisc or Synvisc-One
    2. You meet ONE of the following:
        a. You have tried or have a contraindication to (harmful for you to use) an intra-articular (injected within the joint) steroid (such as methylprednisolone acetate, triamcinolone acetonide)
        b. You have tried or have a contraindication to (harmful for you to use) a topical non- steroidal anti-inflammatory drug (NSAID) (such as diclofenac)
        c. You have tried or have a contraindication to (harmful for you to use) an oral non- steroidal anti-inflammatory drug (NSAID) (such as meloxicam, diclofenac)
        d. You have tried or have a contraindication to (harmful for you to use) acetaminophen

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HYALURONATE

RENEWAL CRITERIA

1. Has the patient received previous treatment on the same knee with Synvisc, Synvisc-One, Hyalgan, Euflexxa, Supartz FX, Synojoynt, Gel-One, Monovisc, Orthovisc, Hymovis, Hymovis One, Gelsyn-3, Genvisc 850, Visco-3, Trivisc, Triluron, Sodium Hyaluronate, OR Durolane?

   If yes, continue to #2.
   If no, refer to Initial Criteria.

2. Has it been at least 6 months since the last treatment with the requested medication?

   If yes, **approve for 6 months by HICL or GPI-10.**If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYALURONATE (Euflexxa, Gel-One, Gelsyn-3, Hyalgan, Hymovis, Hymovis One, Monovisc, Orthovisc, Supartz FX, Synojoynt, Synvisc, Synvisc-One, Genvisc 850, Visco-3, Trivisc, Durolane, Triluron, Sodium Hyaluronate)** requires the following rule(s) be met for renewal:
   A. It has been at least 6 months since your last treatment on the same knee

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HYALURONATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Durolane, Synvisc, Synvisc-One, Hyalgan, Supartz FX, Euflexxa, Gel-One, Gelsyn-3, Orthovisc, Monovisc, Hymovis, Hymovis One, Genvisc 850, Visco-3, Trivisc, Triluron, Sodium Hyaluronate, and Synojoynt.

REFERENCES

Synvisc [Prescribing Information]. Ridgefield, NJ: Genzyme Corporation; March 2010.
Synvisc-One [Prescribing Information]. Ridgefield, NJ: Genzyme Corporation; January 2025.
Hyalgan [Prescribing Information]. Florham Park, NJ: Fidia Pharma USA Inc.; August 2017.
Supartz FX [Prescribing Information]. Durham, NC: Bioventus LLC; March 2016.
Orthovisc [Product Information]. Woburn, MA: Anika Therapeutics Inc.; June 2006.
Monovisc [Prescribing Information]. Bedford, MA: Anika Therapeutics, Inc. (No date available).
Euflexxa [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; July 2016.
Hymovis [Prescribing Information]. Florham Park, NJ: Fidia Pharma USA Inc. (No date available).
Hymovis One [Prescribing Information]. Florham Park, NJ: Fidia Pharma USA Inc; March 2025.
Gel-one [Prescribing Information]. Warsaw, IN: Zimmer Inc.; May 20, 2011.
Gelsyn-3 [Prescribing Information]. Durham, NC: Bioventus LLC; December 2017.
Durolane [Prescribing Information]. Durham, NC: Bioventus LLC. (No date available).
Genvisc 850 Prescribing Information. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140005d.pdf. Accessed December 1, 2025.
Visco-3 Prescribing Information. Available at https://www.accessdata.fda.gov/cdrh_docs/pdf/P980044S027d.pdf. Accessed December 1, 2025.
Trivisc Prescribing Information. Available at https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160057D.pdf. Accessed December 1, 2025.
Triluron [Prescribing Information]. Florham Park, NJ: Fidia Pharma USA Inc.; July 2019.
Sodium Hyaluronate [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.
Synojoynt Summary of safety and effectiveness (SSED). Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170016B.pdf. Accessed December 1, 2025.

Created: 05/14
Effective: 01/01/26 Client Approval: 12/25 P&T Approval: 01/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROCHLOROTHIAZIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROCHLOROTHIAZIDE	INZIRQO	03649		GPI-10 (3760004000)	BRAND = INZIRQO

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow hydrochlorothiazide tablets

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #320mL per 30 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of edema (ICD-10 Group R60) associated with congestive heart failure, hepatic cirrhosis, or renal disease (including nephrotic syndrome) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow hydrochlorothiazide tablets

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #320mL per 30 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYDROCHLOROTHIAZIDE (Inzirqo)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Hypertension (high blood pressure)
      2. Edema (swelling caused by fluid build-up in the body) associated with congestive heart failure (a type of heart condition), hepatic cirrhosis (liver damage and scarring), or renal (kidney) disease (including nephrotic syndrome [a type of kidney disorder])

   B. If you have hypertension, approval also requires:
      1. You have a contraindication to (harmful for you to use) or are unable to swallow hydrochlorothiazide tablets

   C. If you have edema associated with congestive heart failure, hepatic cirrhosis, or renal disease (including nephrotic syndrome), approval also requires:
      1. You have a contraindication to (harmful for you to use) or are unable to swallow hydrochlorothiazide tablets

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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HYDROCHLOROTHIAZIDE

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Inzirqo.

REFERENCES
Inzirqo [Prescribing Information]. Baudette, MN: ANI Pharmaceuticals, Inc.; January 2025.

Created: 03/25
Effective: 04/07/25 Client Approval: 03/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROCORTISONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROCORTISONE	ALKINDI SPRINKLE		46547 46548 46549 46551	GPI-14 (22100025006810) (22100025006815) (22100025006820) (22100025006830)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of adrenocortical insufficiency (ICD-10 E27.40) and meet **ALL** of the following criteria?
   - The patient is less than 18 years of age
   - The patient is unable to take the tablet formulation of hydrocortisone (e.g., need for lower strength, difficulty swallowing)

   If yes, **approve for 6 months for all strengths by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYDROCORTISONE (Alkindi Sprinkle)** requires the following rule(s) be met for approval:
   A. You have adrenocortical insufficiency (a type of hormone disorder)
   B. You are less than 18 years of age
   C. You are unable to take the tablet form of hydrocortisone (such as you need a lower strength, you have difficulty swallowing)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alkindi Sprinkle.

REFERENCES

Alkindi Sprinkle [Prescribing Information]. Baden-Wuerttemberg, Germany: Eton Pharmaceuticals, Inc.; February 2024.

Created: 02/21
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROMORPHONE ER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROMORPHONE HCL	EXALGO, HYDROMORPHONE ER		22056 28427 22098 33088	GPI-12 (651000351075)	EXTENDED RELEASE ONLY

GUIDELINES FOR USE

1. Does the patient meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose of another opioid)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the request form indicate that this medication will be used on an "as needed" or "PRN" basis?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

3. Does the patient require a dosage of 16mg or less?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent (8mg, 12mg, 16mg) for #1 per day. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).**

   If no, continue to #4.

4. Was this dosage recommended by a pain specialist?

   If yes, **approve for 12 months by GPID or GPI-14 (32mg) for #2 per day. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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HYDROMORPHONE ER

GUDIELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **HYDROMORPHONE ER (Exalgo)** requires the following rule(s) be met for approval:

A. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose (equal pain relieving dose) of another opioid
B. The requested medication is not prescribed on an as-needed basis
C. Dosages above 16mg require recommendation from a pain specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exalgo.

REFERENCES

Exalgo [Prescribing Information]. Hazelwood, MO: Mallinckrodt; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/04/22
Created: 04/10
Client Approval: 02/22
P&T Approval: 07/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

HYDROXYUREA-XROMI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
HYDROXYUREA	XROMI	03897		GPI-10 (8280303000)	BRAND = XROMI

GUIDELINES FOR USE

1. Does the patient have a diagnosis of sickle cell anemia (ICD-10 Group D57.0) and meet **ALL** of the following criteria?
   - The patient is 6 months to 17 years of age
   - The patient has recurrent moderate to severe painful crises
   - The patient has a contraindication to or is unable to swallow generic hydroxyurea capsules

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **HYDROXYUREA-XROMI** requires the following rule(s) be met for approval:
   A. You have sickle cell anemia (a type of blood disorder)
   B. You are 6 months to 17 years of age
   C. You have recurrent moderate to severe painful crises (repeated episodes of extreme pain)
   D. You have a contraindication to (harmful for you to use) or are unable to swallow generic hydroxyurea capsules

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xromi.

REFERENCES

Xromi [Prescribing Information]. Franklin, TN: Rare Disease Therapeutics, Inc.; December 2024.

Created: 02/25
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

IBALIZUMAB-UIYK (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IBALIZUMAB-UIYK	TROGARZO	44791		GPI-10 (1210224030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with other antiretroviral(s)
   - The patient is treatment experienced
   - The patient has multidrug-resistant HIV-1 infection
   - The patient is failing their current antiretroviral regimen

   If yes, **approve for 12 months by HICL or GPI-10 as follows:**
   INITIAL REQUEST:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #18.62 mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #10.64mL per 28 days. (Please enter start date 3 WEEKS AFTER the START date of first approval).**

   SUBSEQUENT/CONTINUATION REQUEST:
   - **Approve for 12 months by HICL or GPI-10 with a quantity limit of #10.64mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IBALIZUMAB-UIYK (Trogarzo)** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus type 1 (HIV-1) infection (a virus that attacks the body's immune system and if untreated, can lead to AIDS [acquired immunodeficiency syndrome])
   B. You are 18 years of age or older
   C. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
   D. You are treatment experienced (previously treated)
   E. You have multidrug-resistant HIV-1 infection (your virus is resistant to more than one HIV medication)
   F. You are failing your current antiretroviral regimen

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

IBALIZUMAB-UIYK (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trogarzo.

REFERENCES

Trogarzo [Prescribing Information]. Irvine, CA: TaiMed Biologics USA Corp., March 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/01/20

Created: 08/20
Client Approval:08/20

P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IBREXAFUNGERP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IBREXAFUNGERP CITRATE	BREXAFEMME	47416		GPI-10 (1150704010)	

GUIDELINES FOR USE

1. Is the request for the treatment of vulvovaginal candidiasis (VVC) and the patient meets **ALL** of the following criteria?
   - The patient is a post-menarchal female
   - The patient had a trial of or contraindication to oral fluconazole AND an intravaginal azole (e.g., terconazole cream)

   If yes, **approve for 30 days by HICL or GPI-10 for one fill with a quantity limit of #4.**
   If no, continue to #2.

2. Is the request for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) and the patient meets **ALL** of the following criteria?
   - The patient is a post-menarchal female
   - The patient had a trial of or contraindication to oral fluconazole (the patient had a breakthrough episode of VVC while taking fluconazole 150 mg weekly)
   - The patient is NOT currently on oteseconazole for RVVC

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient previously received Brexafemme?

   If yes, continue to #5.
   If no, continue to #4.

4. Has the patient had 3 or more episodes of VVC in the past 12 months?

   If yes, **approve for 6 months by HICL or GPI-10 for 6 fills total with a quantity limit of #4 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient has successfully completed a course of Brexafemme for prevention of RVVC
   - The patient is either being treated or has just completed treatment for a new recurrence of VVC

   If yes, **approve for 6 months by HICL or GPI-10 for 6 fills total with a quantity limit of #4 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IBREXAFUNGERP (Brexafemme)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Treatment of vulvovaginal candidiasis (VVC: vaginal yeast infection)
      2. Reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC: repeated vaginal yeast infection)

   B. If you are using Brexafemme for the treatment of vulvovaginal candidiasis, approval also requires:
      1. You are a post-menarchal (you have started having your period) female
      2. You have tried or have a contraindication to (harmful for) oral fluconazole AND an intravaginal azole (type of drug that is inserted into the vagina and used to treat yeast infections such as terconazole cream)

   C. If you are using Brexafemme for the reduction in the incidence of recurrent vulvovaginal candidiasis, approval also requires:
      1. You are a post-menarchal (you have started having your period) female
      2. You have tried or have a contraindication to (harmful for) oral fluconazole (you had a breakthrough episode of VVC while taking fluconazole 150 mg weekly)
      3. You are NOT currently on oteseconazole for RVVC
      4. You meet ONE of the following:
         a. You have not previously received Brexafemme AND you had 3 or more episodes of RVVC in the past 12 months
         b. You have been previously treated with Brexafemme and meet ALL of the following:
            i. You have successfully completed a course of Brexafemme for prevention of RVVC
            ii. You are either being treated or have just completed treatment for a new recurrence of VVC

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IBREXAFUNGERP

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brexafemme.

REFERENCES

Brexafemme [Prescribing Information]. Jersey City, NJ: Scynexis, Inc.; November 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23

Created: 07/21
Client Approval: 02/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IBRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IBRUTINIB	IMBRUVICA	40745		GPI-10 (2153213300)	

GUIDELINES FOR USE

1. Is the request for Imbruvica (ibrutinib) 560 mg tablet?

   If yes, do not approve. (**NOTE:** This strength does not have an FDA-approved indication.)
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **70 mg capsule: #1 per day.**
   - **140 mg capsule: #2 per day.**
   - **140 mg tablet: #1 per day.**
   - **280 mg tablet: #1 per day.**
   - **420 mg tablet: #1 per day.**
   - **70 mg/mL oral suspension: #7.2 mL per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of Waldenstrom's macroglobulinemia (WM) (ICD-10 C88.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **70 mg capsule: #1 per day.**
   - **140 mg capsule: #2 per day.**
   - **140 mg tablet: #1 per day.**
   - **280 mg tablet: #1 per day.**
   - **420 mg tablet: #1 per day.**
   - **70 mg/mL oral suspension: #7.2 mL per day.**

   If no, continue to #4.

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IBRUTINIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of chronic graft-versus-host disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has failed at least ONE line of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil)
   - Imbruvica will NOT be used concurrently with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Rezurock (belumosudil)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **70 mg capsule: #1 per day.**
   - **140 mg capsule: #2 per day.**
   - **140 mg tablet: #1 per day.**
   - **280 mg tablet: #1 per day.**
   - **420 mg tablet: #1 per day.**
   - **70 mg/mL oral suspension: #7.2 mL per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IBRUTINIB (Imbruvica)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
      3. Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
      4. Chronic graft-versus-host disease (cGVHD: a type of long-term immune disorder)

   B. If you have chronic lymphocytic leukemia, small lymphocytic lymphoma, or Waldenstrom's macroglobulinemia, approval also requires:
      1. You are 18 years of age or older

   C. If you have chronic graft-versus-host disease, approval also requires:
      1. You are 1 year of age or older
      2. You have failed at least ONE line of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil)
      3. You will NOT use Imbruvica concurrently (at the same time) with Jakafi (ruxolitinib), Niktimvo (axatilimab-csfr), or Rezurock (belumosudil)

   NOTE: Requests for Imbruvica (ibrutinib) 560 mg tablet will not be approved. This strength does not have a Food and Drug Administration (FDA)-approved indication.

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IBRUTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imbruvica.

REFERENCES

Imbruvica [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; December 2024.

Created: 01/14
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ICATIBANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ICATIBANT ACETATE	FIRAZYR, SAJAZIR, ICATIBANT	35962		GPI-10 (8582004010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The requested medication will be used for the treatment of acute attacks of hereditary angioedema
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- The requested medication will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for 12 months (up to 12 fills) by HICL or GPI-10 with a quantity limit of #18mL (#6 syringes) per fill.**
If no, continue to #3.

3. Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
- The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
- Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

If yes, **approve for 12 months (up to 12 fills) by HICL or GPI-10 with a quantity limit of #18mL (#6 syringes) per fill.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ICATIBANT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ICATIBANT (Firazyr, Sajazir)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 18 years of age or older
C. The requested medication will be used for the treatment of acute (sudden and severe) attacks of hereditary angioedema (HAE: a type of gene condition with severe body swelling)
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use the requested medication concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema: a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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ICATIBANT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient has experienced a reduction in the severity or duration of HAE attacks
- The requested medication will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

If yes, **approve for 12 months (up to 12 fills) by HICL or GPI-10 with a quantity limit of #18mL (#6 syringes) per fill.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ICATIBANT (Firazyr, Sajazir)** requires the following rule(s) be met for renewal:
A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced a reduction (decrease) in the severity or duration of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
C. You will NOT use the requested medication concurrently (at the same time) with other medications used for the treatment of acute hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Firazyr and Sajazir.

REFERENCES

Firazyr [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals America, Inc.; June 2025.
Sajazir [Prescribing Information]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; February 2024.

Created: 09/11
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ICOTROKINRA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ICOTROKINRA HCL	ICOTYDE	51213		GPI-10 (9025055020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Icotyde will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, TYK2 inhibitor [e.g., Sotyktu [deucravacitinib], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Icotyde
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ICOTROKINRA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ICOTROKINRA (Icotyde)** requires the following rule(s) be met for approval:

A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
D. You will NOT use Icotyde concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, TYK2 [tyrosine kinase 2] inhibitor [such as Sotyktu (deucravacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
E. You meet ONE of the following:
    1. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
    2. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) AND PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
    3. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
F. You meet ONE of the following:
    1. You were previously stable on another biologic and are switching to Icotyde
    2. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA)
    3. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

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ICOTROKINRA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   - Icotyde will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, TYK2 inhibitor [e.g., Sotyktu [deucravacitinib], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ICOTROKINRA (Icotyde)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
   B. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
   C. You will NOT use Icotyde concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, TYK2 [tyrosine kinase 2] inhibitor [such as Sotyktu (deucravacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Icotyde.

REFERENCES

Icotyde [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; March 2026.

Created: 06/26
Effective: 07/01/26 Client Approval:06/26 DMC Approval: 06/16/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IDELALISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IDELALISIB	ZYDELIG	41297		GPI-10 (2153804000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) **AND** meet the following criterion?
   - Zydelig will be used in combination with rituximab

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IDELALISIB (Zydelig)** requires the following rule(s) be met for approval:
   A. You have relapsed (disease has returned) chronic lymphocytic leukemia (CLL: a type of blood cancer)
   B. Zydelig will be used in combination with rituximab

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Zydelig.

REFERENCES

Zydelig [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; February 2022.

Created: 08/14
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 11/14

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ILOPROST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ILOPROST TROMETHAMINE	VENTAVIS	26287		GPI-10 (4017006000)	BRAND = VENTAVIS

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient had a trial of or contraindication to **TWO** of the following clinical standard of care agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ILOPROST

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
D. You have tried or have a contraindication to (harmful for you to use) TWO of the following clinical standard of care medications from different drug classes:
    1. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
    2. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
    3. Oral cGMP stimulator (such as Adempas [riociguat])
    4. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ILOPROST

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Ventavis.

REFERENCES

Ventavis [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2022.

Created: 01/08
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMATINIB MESYLATE	GLEEVEC, IMKELDI, IMATINIB MESYLATE	22096		GPI-10 (2153183510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1) and meet **ONE** of the following criteria?
   - The Ph+ CML is in chronic phase AND the patient is newly diagnosed (e.g., starting or previously started the requested treatment at the time of diagnosis)
   - The Ph+ CML is in blast crisis (BC), accelerated phase (AP), or chronic phase (CP), AND the patient has failed interferon-alpha therapy

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has NOT received previous treatment with another tyrosine kinase inhibitor [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)]
   - The patient had a mutational analysis prior to initiation of therapy AND the requested medication is appropriate based on the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Gleevec (imatinib) tablet?

   If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **400mg: #2 per day.**
   - **100mg: #6 per day.**

   If no, continue to #20.

4. Does the patient have a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0)?

   If yes, continue to #5.
   If no, continue to #7.

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GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient is 18 years of age or older AND has relapsed or refractory Ph+ ALL
   - The patient is newly diagnosed (e.g., starting or previously started the requested treatment at the time of diagnosis) AND the requested medication will be used in combination with chemotherapy

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is the request for Gleevec (imatinib) tablet?

   If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **400mg: #1 per day.**
   - **100mg: #6 per day.**

   If no, continue to #20.

7. Does the patient have a diagnosis of a myelodysplastic/myeloproliferative disease (MDS/MPD) (ICD-10 C94.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's disease is associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements

   If yes, continue to #8.
   If no, continue to #9.

8. Is the request for Gleevec (imatinib) tablet?

   If yes, **approve Gleevec (imatinib) 400mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, continue to #20.

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM) (ICD-10 C96.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's disease is without the D816V c-Kit mutation or the c-Kit mutational status is unknown

   If yes, continue to #10.
   If no, continue to #11.

10. Is the request for Gleevec (imatinib) tablet?

    If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
    - **400mg: #1 per day.**
    - **100mg: #3 per day.**

    If no, continue to #20.

11. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and/or chronic eosinophilic leukemia (CEL) (ICD-10 C94.8) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #12.
    If no, continue to #13.

12. Is the request for Gleevec (imatinib) tablet?

    If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
    - **400mg: #1 per day.**
    - **100mg: #3 per day.**

    If no, continue to #20.

13. Does the patient have a diagnosis of unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (DFSP) (ICD-10 C44.99) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #14.
    If no, continue to #15.

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

14. Is the request for Gleevec (imatinib) tablet?

    If yes, **approve Gleevec (imatinib) for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
    - **400mg: #2 per day.**
    - **100mg: #6 per day.**

    If no, continue to #20.

15. Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) **AND** meet the following criterion?
    - The patient's tumor is Kit (CD117) positive

    If yes, continue to #16.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

16. Does the patient meet **ONE** of the following criteria?
    - The patient's cancer is unresectable and/or metastatic malignant
    - The patient is 18 years of age or older AND the requested medication will be used as adjuvant treatment following complete gross resection

    If yes, continue to #17.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

17. Is the request for Gleevec (imatinib) tablet?

    If yes, continue to #18.
    If no, continue to #20.

18. Is the request for a dosage of 400mg twice daily?

    If yes, continue to #19.
    If no, **approve Gleevec (imatinib) as follows:**
    - **Adjuvant GIST treatment: approve 400mg for 36 months by GPID or GPI-14 with a quantity limit of #1 per day.**
    - **Unresectable and/or metastatic malignant GIST: approve 400mg for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

19. Has the patient tried Gleevec (imatinib) 400mg once daily **OR** does the patient have GIST tumor expressing a KIT exon 9 mutation?

    If yes, **approve Gleevec (imatinib) as follows:**
    - **Adjuvant GIST treatment: approve 400mg for 36 months by GPID or GPI-14 with a quantity limit of #2 per day.**
    - **Unresectable and/or metastatic malignant GIST: approve 400mg for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

20. Is the request for Imkeldi 80mg/mL solution **AND** the patient meets the following criterion?
    - The patient is unable to swallow generic imatinib tablets

    If yes, **approve Imkeldi by GPID or GPI-14 with a quantity limit of #280mL per 28 days as follows:**
    - **Adjuvant GIST treatment: approve for 36 months.**
    - **All other indications: approve for 12 months.**

    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **IMATINIB (Gleevec, Imkeldi)** requires the following rule(s) be met for approval:
    A. You have ONE of the following:
        1. Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML: a type of blood cancer)
        2. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cancer)
        3. Myelodysplastic/myeloproliferative disease (MDS/MPD: a type of blood cancer)
        4. Aggressive systemic mastocytosis (ASM: a type of blood disorder)
        5. Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) (types of inflammatory cancer)
        6. Dermatofibrosarcoma protuberans (DFSP: a type of rare skin tumor)
        7. Gastrointestinal stromal tumor (GIST: type of digestive tumor)
    B. If the request is for Imkeldi solution, approval also requires that you are unable to swallow generic imatinib tablets

    (Denial text continued on next page)

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

C. If you have Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML), approval also requires:
1. You meet ONE of the following:
   a. Your Ph+ CML is in chronic phase AND you are newly diagnosed (such as you are starting or previously started the requested treatment at the time your condition was identified)
   b. Your Ph+ CML is in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy
2. You have NOT received previous treatment with another tyrosine kinase inhibitor (such as Tasigna [nilotinib], Sprycel [dasatinib], Bosulif [bosutinib], Iclusig [ponatinib])
3. You had a mutational analysis (a type of lab test) prior to the start of therapy AND the requested medication is appropriate based on the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

D. If you have Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:
1. You meet ONE of the following:
   a. You are 18 years of age or older, AND your Ph+ ALL has relapsed or is refractory (cancer that has returned or has not responded to treatment)
   b. You are newly diagnosed (such as you are starting or previously started the requested treatment at the time your condition was identified) AND the requested medication will be used in combination with chemotherapy (a type of cancer treatment)

E. If you have myelodysplastic/myeloproliferative disease, approval also requires:
1. You are 18 years of age or older
2. Your disease is associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements (a type of gene mutation)

F. If you have aggressive systemic mastocytosis, approval also requires:
1. You are 18 years of age or older
2. Your disease is without the D816V c-Kit mutation (abnormal change in a type of gene) or the c-Kit mutational status is unknown

G. If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:
1. You are 18 years of age or older

H. If you have dermatofibrosarcoma protuberans, approval also requires:
1. You are 18 years of age or older
2. Your cancer is unresectable, recurrent, and/or metastatic (cancer that cannot be completely removed by surgery, has returned, and/or has spread to other parts of the body)

(Denial text continued on next page)

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IMATINIB

GUIDELINES FOR USE (CONTINUED)

I. If you have gastrointestinal stromal tumor (GIST), approval also requires:
1. Your tumor is Kit (CD117: a type of protein) positive
2. You meet ONE of the following:
   a. Your cancer is unresectable and/or metastatic malignant (cannot be completely removed by surgery and/or has spread to other parts of the body)
   b. You are 18 years of age or older AND the requested medication will be used as adjuvant (additional) treatment following complete gross resection (removal by surgery)
3. For requests of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a gastrointestinal stromal tumor (GIST: type of digestive tumor) expressing a KIT exon 9 mutation (abnormal change in a type of gene)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gleevec and Imkeldi.

REFERENCES

Gleevec [Prescribing Information] East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2026.
Imkeldi [Prescribing Information] Cambridge, MA: Shorla Oncology Inc.; November 2024.

Created: 11/11
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMETELSTAT (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMETELSTAT SODIUM	RYTELO	49663		GPI-10 (2153532560)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of myelodysplastic syndrome (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is low- to intermediate-1 risk
   - The patient has transfusion-dependent anemia requiring at least 4 red blood cell (RBC) units over 8 weeks
   - The patient's cancer is unresponsive to erythropoiesis-stimulating agents (ESA) (e.g., Epogen [epoetin alfa]) OR the patient is ESA ineligible

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMETELSTAT (Rytelo)** requires the following rule(s) be met for approval:
   A. You have myelodysplastic syndrome (MDS: a type of blood cancer)
   B. You are 18 years of age or older
   C. Your cancer is low- to intermediate-1 risk
   D. You have transfusion-dependent anemia (a type of blood condition) requiring at least 4 red blood cell (RBC) units over 8 weeks
   E. Your cancer did not respond to treatment with erythropoiesis-stimulating agents (ESA: a type of medication that increases the production of red blood cells, such as Epogen [epoetin alfa]) OR you are not able to be treated with ESA

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rytelo.

REFERENCES

Rytelo [Prescribing Information]. Foster City, CA: Geron Corporation; June 2024.

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 07/24
Client Approval: 07/24
P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMIGLUCERASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMIGLUCERASE	CEREZYME	09022		GPI-10 (8270005000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Gaucher disease (ICD-10 E75.22) and meet **ALL** of the following criteria?
   - The patient has non-central nervous system (CNS) manifestations
   - The patient has Type 1 or Type 3 Gaucher disease

   If yes, **approve for up to 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMIGLUCERASE (Cerezyme)** requires the following rule(s) be met for approval:
   A. You have Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
   B. You have non-central nervous system (CNS) manifestations (symptoms not involving the brain and spinal cord)
   C. You have Type 1 (no brain involvement) or Type 3 (slowly progressive brain involvement) Gaucher disease

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cerezyme.

REFERENCES

Cerezyme [Prescribing Information]. Cambridge, MA: Genzyme Corporation; January 2026.

Created: 05/05
Effective: 02/09/26 Client Approval: 01/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMLUNESTRANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMLUNESTRANT TOSYLATE	INLURIYO	50911		GPI-10 (2140353670)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The disease is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor-1 (ESR1) gene mutation(s)
   - The patient has had disease progression following at least ONE line of endocrine therapy (e.g., anastrozole, letrozole)
   - Therapy is prescribed by or in consultation with an oncology specialist
   - Inluriyo will NOT be used concurrently with another selective estrogen receptor degrader (SERD) (e.g., Orserdu [elacestrant], Faslodex [fulvestrant], Veppanu [vepdegestrant])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT:

   Our guideline named **IMLUNESTRANT (Inluriyo)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. Your disease is estrogen receptor (ER: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene)
   C. You have had disease progression (worsening) following at least ONE line of endocrine therapy (a type of hormone therapy such as anastrozole, letrozole)
   D. Therapy is prescribed by or in consultation with an oncology specialist (a type of cancer doctor)
   E. You will NOT use Inluriyo concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Orserdu [elacestrant], Faslodex [fulvestrant], Veppanu [vepdegestrant])

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMLUNESTRANT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The disease is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor-1 (ESR1) gene mutation(s)
   - The patient has demonstrated clinical benefit while on therapy as shown by a partial or complete response OR stable disease
   - Inluriyo will NOT be used concurrently with another selective estrogen receptor degrader (SERD) (e.g., Orserdu [elacestrant], Faslodex [fulvestrant], Veppanu [vepdegestrant])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **IMLUNESTRANT (Inluriyo)** requires the following rule(s) be met for renewal:
   A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. Your disease is estrogen receptor (ER: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene)
   C. You have experienced clinical benefit while on therapy as shown by a partial (cancer has shrunk but did not go away) or complete response (cancer went away completely) OR stable disease (disease has stopped growing or spreading)
   D. You will NOT use Inluriyo concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Orserdu [elacestrant], Faslodex [fulvestrant], Veppanu [vepdegestrant])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inluriyo.

REFERENCES

Inluriyo [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; October 2025.

Created: 10/25
Effective: 08/21/26 Client Approval: 08/26 DMC Approval: 08/11/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN - GAMASTAN (S-D)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUNE GLOBUL G (IGG)/GLYCINE	GAMASTAN, GAMASTAN S-D		43715	GPI-10 (1910002000)	

GUIDELINES FOR USE

1. Is the requested medication being used for the prophylaxis or passive immunization of hepatitis A, measles, varicella, or rubella?

   If yes, **approve the requested agent for 12 months by GPID or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMMUNE GLOBULIN - GAMASTAN (S-D)** requires the following rule(s) be met for approval:
   A. You are using the requested drug for prophylaxis (prevention) or passive immunization (immune response where antibodies are obtained from outside the body) of hepatitis A, measles, varicella, or rubella (types of viral infections)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gamastan, Gamastan S-D.

REFERENCES

Gamastan [Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics LLC; August 2022.
Gamastan S-D [Prescribing Information]. Research Triangle Park, NC: Grifols; August 2022.

Created: 05/24
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 10/12

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUNE GLOBULIN (HUMAN) IV	ALYGLO	49343		GPI-10 (1910002083)	
	ASCENIV	46208		GPI-10 (1910002080)	
	BIVIGAM, FLEBOGAMMA DIF, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN	04202 41995 41798		GPI-10 (1910002010)	BRAND = BIVIGAM, FLEBOGAMMA DIF, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN
	OCTAGAM	33220			MEDISPAN: BRAND = OCTAGAM
	PANZYGA	45354		GPI-10 (1910002060)	
	QIVIGY	50913		GPI-10 (1910002084)	
	YIMMUGO	49682		GPI-10 (1910002051)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83)
   - Immune (idiopathic) thrombocytopenic purpura (ITP) (ICD-10 D69.3)
   - Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81)
   - Multifocal motor neuropathy (MMN) (ICD-10 G61.82)
   - Kawasaki syndrome (ICD-10 M30.3)
   - B-cell chronic lymphocytic leukemia (CLL) with hypogammaglobulinemia
   - Autoimmune hemolytic anemia (AIHA) (ICD-10 Group D59.1)
   - Pure red cell aplasia (PRCA) (ICD-10 D61.01)
   - Guillain-Barre syndrome (GBS) (ICD-10 G61.0)
   - Myasthenia gravis (ICD-10 Group G70.0)
   - Autoimmune Graves' ophthalmopathy (ICD-10 E05.00)
   - Cytomegalovirus-induced pneumonitis (ICD-10 B25.0) related to a solid organ transplant
   - Prevention of bacterial infection in an HIV-infected child
   - Reduction of secondary infections in pediatric HIV infections
   - Dermatomyositis or polymyositis (ICD-10 M36.0, Group M33)
   - Autoimmune uveitis (birdshot retinochoroidopathy)
   - Lambert-Eaton myasthenic syndrome (ICD-10 G70.80)

   (List continued on next page)

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IMMUNE GLOBULIN - IV

GUIDELINES FOR USE (CONTINUED)

- IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
- Stiff-man syndrome (ICD-10 G25.82)
- Neonatal sepsis (ICD-10 Group P36)
- Rotaviral enterocolitis (ICD-10 A08.0)
- Toxic shock syndrome (ICD-10 A48.3)
- Enteroviral meningoencephalitis (ICD-10 A87.0, A85.0)
- Toxic epidermal necrolysis (ICD-10 L51.2) or Stevens-Johnson syndrome (ICD-10 L51.1, L51.3)
- Autoimmune mucocutaneous blistering disease (AMBD) (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

  If yes, continue to #2.
  If no, do not approve.
  DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Gammagard S-D, Octagam or Privigen?

   If yes, **approve the requested medication for 12 months as follows:**
   - **Gammagard S-D: Approve all strengths by GPID or GPI-14.**
   - **Octagam: Approve by HICL or NDC (Medi-Span).**
   - **Privigen: Approve by NDC (FDB or Medi-Span).**

   If no, continue to #3.

3. Is the request for Alyglo, Asceniv, Bivigam, Flebogamma DIF, Gammaplex, Panzyga, Qivigy, or Yimmugo?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IMMUNE GLOBULIN - IV

GUIDELINES FOR USE (CONTINUED)

4. Has the patient had a trial of or contraindication to **TWO** of the following preferred agents: Gammagard S-D, Gammagard (Liquid), Gammagard Liquid ERC, Gamunex-C, Octagam, Privigen?

   If yes, **approve the requested medication for 12 months as follows:**
   - **Alyglo: Approve by HICL or GPI-10.**
   - **Asceniv: Approve by HICL or GPI-10.**
   - **Bivigam: Approve by GPID or GPI-10.**
   - **Flebogamma DIF: Approve by GPID or GPI-10.**
   - **Gammaplex: Approve by GPID or GPI-10.**
   - **Panzyga: Approve by HICL or GPI-10.**
   - **Qivigy: Approve by HICL or GPI-10.**
   - **Yimmugo: Approve by HICL or GPI-10.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IMMUNE GLOBULIN - IV (Alyglo, Asceniv, Bivigam, Flebogamma DIF, Gammagard S-D, Gammaplex, Octagam, Panzyga, Privigen, Qivigy, Yimmugo)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Primary immunodeficiency disease (genetic disease where the immune system is weak)
      2. Immune (idiopathic) thrombocytopenic purpura (a type of blood disorder)
      3. Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
      4. Multifocal motor neuropathy (MMN: a nerve disorder with increasing muscle weakness)
      5. Kawasaki syndrome (inflammation in the walls of blood vessels in the body)
      6. B-cell chronic lymphocytic leukemia (CLL: blood and bone marrow cancer of immune cells) with hypogammaglobulinemia (low levels of immunoglobulins)
      7. Autoimmune hemolytic anemia (AIHA: body destroys red blood cells more rapidly than it produces them)
      8. Pure red cell aplasia (PRCA: bone marrow stops making red blood cells)
      9. Guillain-Barre syndrome (GBS: immune system attacks the nerves)
      10. Myasthenia gravis (a type of chronic autoimmune disorder)

   (Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

11. Autoimmune Graves' ophthalmopathy (a type of eye disease)
12. Cytomegalovirus-induced pneumonitis (lung tissue inflammation caused by a virus) related to a solid organ transplant
13. Prevention of bacterial infection in an HIV (human immunodeficiency virus: an immune system disease caused by a virus)- infected child
14. Reduction of secondary infections in pediatric HIV (human immunodeficiency virus: an immune system disease caused by a virus) infections
15. Dermatomyositis (a type of muscle and skin disorder) or polymyositis (a type of inflammatory muscle disease)
16. Autoimmune uveitis (birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
17. Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
18. IgM (immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (a type of nerve damage)
19. Stiff-man syndrome (a nerve disorder with increasing muscle stiffness [rigidity] and repeated episodes of painful muscle spasms)
20. Neonatal sepsis (blood infection in infants)
21. Rotaviral enterocolitis (severe diarrhea among infants and young children)
22. Toxic shock syndrome (a life-threatening complication of certain bacterial infections)
23. Enteroviral meningoencephalitis (inflammation of the brain and surrounding tissues caused by a virus)
24. Toxic epidermal necrolysis or Stevens-Johnson syndrome (types of serious bacterial skin infections)
25. Autoimmune mucocutaneous blistering disease (AMBD) (group of serious skin conditions that start with blisters on the skin such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

B. If the request is for Alyglo, Asceniv, Bivigam, Flebogamma DIF, Gammaplex, Panzyga, Qivigy, or Yimmugo approval also requires:

1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Gammagard S-D, Gammagard (Liquid), Gammagard Liquid ERC, Gamunex-C, Octagam, Privigen

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IMMUNE GLOBULIN - IV

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alyglo, Asceniv, Bivigam, Flebogamma DIF, Gammagard S-D, Gammaplex, Octagam, Panzyga, Privigen, Qivigy, or Yimmugo.

REFERENCES

Alyglo [Prescribing Information]. Teaneck, NJ: GC Biopharma USA, Inc.; December 2023.
Asceniv [Prescribing Information]. Boca Raton, FL: ADMA Biologics; April 2025.
Bivigam [Prescribing Information]. Boca Raton, FL: ADMA Biologics, Inc.; April 2025.
Flebogamma DIF [Prescribing Information]. Barcelona, Spain: Instituto Grifols, S.A.; September 2019.
Gammagard S-D [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; February 2025.
Gammaplex [Prescribing Information]. Fort Lee, NJ: Kedrion Biopharma, Inc.; May 2024.
Octagam [Prescribing Information]. New York, NY: Pfizer Inc.; January 2024.
Panzyga [Prescribing Information]. Paramus, NJ: Octapharma USA, Inc.; February 2021.
Privigen [Prescribing Information]. Kankakee, IL: CSL Behring LLC; May 2025.
Qivigy [Prescribing Information]. Fort Lee, NJ: Kedrion Biopharma Inc.; September 2025.
Yimmugo [Prescribing Information]. Los Angeles, CA: Grifols; June 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN - IV/SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUN GLOB G(IGG)/GLY/IGA OV50	GAMMAGARD LIQUID	04202		GPI-10 (1910002030)	FDB: BRAND = GAMMAGARD LIQUID
IMMUNE GLOBUL G/GLY/IGA AVG 46	GAMMAKED, GAMUNEX-C	25631			
IMMUN GLOB G(IGG)/GLY/IGA 0-50	GAMMAGARD LIQUID ERC	41995			FDB: BRAND = GAMMAGARD LIQUID ERC MS: BRAND = GAMMAGARD ERC

GUIDELINES FOR USE

1. Is the request for use as a subcutaneous (SQ) injection?

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have **ONE** of the following diagnoses?
   - Primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83)
   - Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Gammagard (Liquid), Gammagard Liquid ERC, or Gamunex-C?

   If yes, **approve the requested medication for 12 months as follows:**
   - **Gammagard (Liquid): Approve by NDC (FDB or Medi-Span).**
   - **Gamunex-C: Approve by NDC (FDB or Medi-Span).**
   - **Gammagard Liquid ERC: Approve by GPID or NDC (Medi-Span).**

   If no, continue to #4.

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IMMUNE GLOBULIN - IV/SQ

GUIDELINES FOR USE (CONTINUED)

4. Is the request for Gammaked **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Gamunex-C, Gammagard (Liquid), Gammagard Liquid ERC, Xembify

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for use as an intravenous (IV) injection?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have **ONE** of the following diagnoses?
   - Primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83)
   - Immune (idiopathic) thrombocytopenic purpura (ITP) (ICD-10 D69.3)
   - Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81)
   - Multifocal motor neuropathy (MMN) (ICD-10 G61.82)
   - Kawasaki syndrome (ICD-10 M30.3)
   - B-cell chronic lymphocytic leukemia (CLL) with hypogammaglobulinemia
   - Autoimmune hemolytic anemia (AIHA) (ICD-10 Group D59.1)
   - Pure red cell aplasia (PRCA) (ICD-10 D61.01)
   - Guillain-Barre syndrome (GBS) (ICD-10 G61.0)
   - Myasthenia gravis (ICD-10 Group G70.0)
   - Autoimmune Graves' ophthalmopathy (ICD-10 E05.00)
   - Cytomegalovirus-induced pneumonitis (ICD-10 B25.0) related to a solid organ transplant
   - Prevention of bacterial infection in an HIV-infected child
   - Reduction of secondary infections in pediatric HIV infections
   - Dermatomyositis or polymyositis (ICD-10 M36.0, Group M33)
   - Autoimmune uveitis (birdshot retinochoroidopathy)
   - Lambert-Eaton myasthenic syndrome (ICD-10 G70.80)

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GUIDELINES FOR USE (CONTINUED)

- IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
- Stiff-man syndrome (ICD-10 G25.82)
- Neonatal sepsis (ICD-10 Group P36)
- Rotaviral enterocolitis (ICD-10 A08.0)
- Toxic shock syndrome (ICD-10 A48.3)
- Enteroviral meningoencephalitis (ICD-10 A87.0, A85.0)
- Toxic epidermal necrolysis (ICD-10 L51.2) or Stevens-Johnson syndrome (ICD-10 L51.1, L51.3)
- Autoimmune mucocutaneous blistering disease (AMBD) (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

If yes, continue to #7.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the request for Gammagard (Liquid), Gammagard Liquid ERC, or Gamunex-C?

If yes, **approve the requested medication for 12 months as follows:**
- **Gammagard (Liquid): Approve by NDC (FDB or Medi-Span).**
- **Gamunex-C: Approve by NDC (FDB or Medi-Span).**
- **Gammagard Liquid ERC: Approve by GPID or NDC (Medi-Span).**

If no, continue to #8.

8. Is the request for Gammaked **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Gammagard S-D, Gammagard (Liquid), Gammagard Liquid ERC, Gamunex-C, Octagam, Privigen

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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IMMUNE GLOBULIN - IV/SQ

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IMMUNE GLOBULIN - IV/SQ (Gammagard [Liquid], Gamunex-C, Gammaked, Gammagard Liquid ERC)** requires the following rule(s) be met for approval:

A. For subcutaneous (SQ) injection, approval requires:

1. You have ONE of the following:
   a. Primary immunodeficiency disease (genetic disease where the immune system is weak)
   b. Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
2. If the request is for Gammaked, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Gamunex-C, Gammagard (Liquid), Gammagard Liquid ERC, Xembify

B. For intravenous (IV) injection, approval requires:

1. You have ONE of the following:
   a. Primary immunodeficiency disease (genetic disease where the immune system is weak)
   b. Immune (idiopathic) thrombocytopenic purpura (a type of blood disorder)
   c. Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
   d. Multifocal motor neuropathy (MMN: a nerve disorder with increasing muscle weakness)
   e. Kawasaki syndrome (inflammation in the walls of blood vessels in the body)
   f. B-cell chronic lymphocytic leukemia (CLL: blood and bone marrow cancer of immune cells) with hypogammaglobulinemia (low levels of immunoglobulins)
   g. Autoimmune hemolytic anemia (AIHA: body destroys red blood cells more rapidly than it produces them)
   h. Pure red cell aplasia (PRCA: bone marrow stops making red blood cells)
   i. Guillain-Barre syndrome (GBS: immune system attacks the nerves)
   j. Myasthenia gravis (a type of chronic autoimmune disorder)
   k. Autoimmune Graves' ophthalmopathy (a type of eye disease)
   l. Cytomegalovirus-induced pneumonitis (lung tissue inflammation caused by a virus) related to a solid organ transplant
   m. Prevention of bacterial infection in an HIV (human immunodeficiency virus: an immune system disease caused by a virus)- infected child
   n. Reduction of secondary infections in pediatric HIV (human immunodeficiency virus: an immune system disease caused by a virus) infections

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

o. Dermatomyositis (a type of muscle and skin disorder) or polymyositis (a type of inflammatory muscle disease)
p. Autoimmune uveitis (birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
q. Lambert-Eaton myasthenic syndrome (a type of muscle disorder)
r. IgM (immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (a type of nerve damage)
s. Stiff-man syndrome (a nerve disorder with increasing muscle stiffness [rigidity] and repeated episodes of painful muscle spasms)
t. Neonatal sepsis (blood infection in infants)
u. Rotaviral enterocolitis (severe diarrhea among infants and young children)
v. Toxic shock syndrome (a life-threatening complication of certain bacterial infections)
w. Enteroviral meningoencephalitis (inflammation of the brain and surrounding tissues caused by a virus)
x. Toxic epidermal necrolysis or Stevens-Johnson syndrome (types of serious bacterial skin infections)
y. Autoimmune mucocutaneous blistering disease (AMBD) (group of serious skin conditions that start with blisters on the skin such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)

2. If the request is for Gammaked, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Gammagard S-D, Gammagard (Liquid), Gammagard Liquid ERC, Gamunex-C, Octagam, Privigen

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gammagard Liquid, Gammagard Liquid ERC, Gammaked, and Gamunex-C.

REFERENCES

Gammagard Liquid [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; September 2024.
Gammagard Liquid ERC [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; October 2025.
Gammaked [Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2020.
Gamunex-C [Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2020.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IMMUNE GLOBULIN (HUMAN) SUBCUTANEOUS	CUTAQUIG	45734		GPI-10 (1910002057)	
	CUVITRU	41796		GPI-10 (1910002020)	
	HIZENTRA	04202 41798			FDB: BRAND = HIZENTRA
	HYQVIA	41391		GPI-10 (1999000235)	
	XEMBIFY	45891		GPI-10 (1910002064)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Primary immunodeficiency disease (PID) (ICD-10 Group D80, Group D81 except Group D81.3 and Group D81.81; ICD-10 D81.82, ICD-10 D81.89, Group D82 except ICD-10 D82.3; Group D83)
   - Chronic inflammatory demyelinating polyneuropathy (CIDP) (ICD-10 G61.81)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Xembify?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the request for Cutaquig, Cuvitru, Hizentra, or Hyqvia?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient had a trial of or contraindication to **TWO** of the following preferred agents: Gamunex-C, Gammagard (Liquid), Gammagard Liquid ERC, Xembify?

   If yes, **approve the requested medication for 12 months as follows:**
   - **Cutaquig: Approve by HICL or GPI-10.**
   - **Cuvitru: Approve by HICL or GPI-10.**
   - **Hizentra: Approve by GPID for all strengths or by GPI-10.**
   - **Hyqvia: Approve by HICL or GPI-10.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IMMUNE GLOBULIN - SQ

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IMMUNE GLOBULIN - SQ (Cutaquig, Cuvitru, Hizentra, Hyqvia, Xembify)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary immunodeficiency disease (genetic disease where the immune system is weak)
   2. Chronic inflammatory demyelinating polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

B. If the request is for Cutaquig, Cuvitru, Hizentra, or Hyqvia, approval also requires:
   1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Gamunex-C, Gammagard (Liquid), Gammagard Liquid ERC, Xembify

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cutaquig, Cuvitru, Hizentra, Hyqvia, or Xembify.

REFERENCES

Cutaquig [Prescribing Information]. Paramus, NJ: Octapharma USA, Inc.; November 2021.
Cuvitru [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; February 2025.
Hizentra [Prescribing Information]. Kankakee, IL: CSL Behring LLC; April 2023.
Hyqvia [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; January 2024.
Xembify [Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics LLC; July 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INAVOLISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INAVOLISIB	ITOVEBI	49923		GPI-10 (2153804500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   - The patient's tumor has a PIK3CA mutation as detected by an FDA-approved test
   - Itovebi will be used in combination with palbociclib (Ibrance) and fulvestrant (Faslodex)
   - The patient has experienced disease recurrence on or after completing adjuvant endocrine therapy (e.g., letrozole, anastrozole, tamoxifen)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **3mg: #2 per day.**
   - **9mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INAVOLISIB (Itovebi)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic breast cancer (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   C. Your tumor has a PIK3CA mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   D. Itovebi will be used in combination with palbociclib (Ibrance) and fulvestrant (Faslodex)
   E. You have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INAVOLISIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Itovebi.

REFERENCES

Itovebi [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; January 2025.

Created: 11/24
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INCOBOTULINUM TOXIN A

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INCOBOTULINUM TOXIN A	XEOMIN	36687		GPI-10 (7440002020)	

GUIDELINES FOR USE

1. Is the request for a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines) (ICD-10 L98.8)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic sialorrhea (drooling or excessive salivation) (ICD-10 K11.7) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **50 unit: #2 vials every 4 months.**
   - **100 unit: #1 vial every 4 months.**

   If no, continue to #3.

3. Does the patient have a diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) (ICD-10 G24.3) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **50 unit: #3 vials every 3 months.**
   - **100 unit: #2 vials every 3 months.**
   - **200 unit: #2 vials every 3 months.**

   If no, continue to #4.

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INCOBOTULINUM TOXIN A

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of blepharospasm (involuntary forcible closure of the eyelid) (ICD-10 G24.5) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **50 unit: #3 vials every 3 months.**
   - **100 unit: #2 vials every 3 months.**
   - **200 unit: #2 vials every 3 months.**

   If no, continue to #5.

5. Does the patient have a diagnosis of upper limb spasticity (ICD-10 G04.1, G11.4, G80.0, G80.1, G80.2; Group G81.1) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **50 unit: #3 vials every 3 months.**
   - **100 unit: #2 vials every 3 months.**
   - **200 unit: #2 vials every 3 months.**

   If no, do not approve.

   DENIAL TEXT: Our guideline named **INCOBOTULINUM TOXIN A (Xeomin)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Chronic sialorrhea (drooling or excessive salivation)
      2. Cervical dystonia (a type of muscle condition)
      3. Blepharospasm (a type of eye disease)
      4. Upper limb spasticity (stiffness or tightness of your muscles)

   B. If you have chronic sialorrhea or upper limb spasticity, approval also requires:
      1. You are 2 years of age or older

   C. If you have cervical dystonia or blepharospasm, approval also requires:
      1. You are 18 years of age or older

   NOTE: This medication will not be approved for a cosmetic indication (for example wrinkles - glabellar lines [wrinkle between the eyebrows], lateral canthal lines [wrinkles in outer corner of eye], forehead lines).

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INCOBOTULINUM TOXIN A

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeomin

REFERENCES
Xeomin [Prescribing Information]. Raleigh, NC: Merz Pharmaceuticals, LLC; June 2026.

Created: 10/22
Effective: 07/15/26 Client Approval: 07/26 DMC Approval: 07/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INEBILIZUMAB-CDON

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INEBILIZUMAB-CDON	UPLIZNA	46617		GPI-10 (9940504020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ophthalmologist
   - The patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
   - Uplizna will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have at least **ONE** of the following core clinical characteristics?
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #60mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #30mL per 6 months (Enter a start date 5 months AFTER THE END DATE of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INEBILIZUMAB-CDON

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of Immunoglobulin G4-related disease (IgG4-RD) (ICD-10 D89.84) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #60mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #30mL per 6 months (Enter a start date 5 months AFTER THE END DATE of the first approval).**

   If no, continue to #4.

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient's diagnosis is confirmed by a positive serologic test for anti-acetylcholine receptor antibody (AChR-Ab+) OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+)
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - Uplizna will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]) or complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of gMG
   - The patient had a trial of or contraindication to ONE standard of care corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod- hyaluronidase-qvfc)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INEBILIZUMAB-CDON

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO standard of care non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
   - The patient had a trial of or contraindication to ONE standard of care non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #60mL per 28 days for one fill.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INEBILIZUMAB-CDON (Uplizna)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
      2. Immunoglobulin G4-related disease (IgG4-RD: a type of inflammatory disorder)
      3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)

   B. If you have neuromyelitis optica spectrum disorder, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
      3. You have a positive serologic (blood) test for the anti-aquaporin-4 (AQP4: a type of protein) antibody
      4. You will NOT use Uplizna concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])
      5. You have at least ONE of the following core clinical characteristics:
         a. Optic neuritis (a type of brain disorder)
         b. Acute myelitis (a type of brain disorder)
         c. Area postrema syndrome (a type of brain disorder)
         d. Acute brainstem syndrome (a type of brain disorder)
         e. Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (a type of brain disorder) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
         f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   (Initial denial text continued on next page)

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INEBILIZUMAB-CDON

INITIAL CRITERIA (CONTINUED)

C. If you have Immunoglobulin G4-related disease, approval also requires:
1. You are 18 years of age or older

D. If you have generalized myasthenia gravis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
3. Your diagnosis is confirmed by a positive serologic test (a type of blood test) for anti-acetylcholine receptor antibody (AChR-Ab+: an indicator of myasthenia gravis) OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+: an indicator of myasthenia gravis)
4. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
5. You will NOT use Uplizna concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]) or complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis (a chronic autoimmune disorder)
6. You have tried or have a contraindication to (harmful for you to use) ONE standard of care corticosteroid (such as prednisone)
7. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)
8. You meet ONE of the following criteria:
   a. You have tried or have a contraindication to (harmful for you to use) TWO standard of care non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
   b. You have tried or have a contraindication to (harmful for you to use) ONE standard of care non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange (types of blood therapy)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INEBILIZUMAB-CDON

RENEWAL CRITERIA

NOTE: For the diagnosis of Immunoglobulin G4-related disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit (reduction in relapse frequency from baseline or a decrease in NMOSD-related hospitalizations)
   - Uplizna will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30mL per 6 months.**

   If no, continue to #2.

2. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Uplizna will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]) or complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #30mL per 6 months.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INEBILIZUMAB-CDON

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INEBILIZUMAB-CDON (Uplizna)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
   2. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)

B. If you have neuromyelitis optica spectrum disorder, renewal also requires:
   1. You have experienced a clinical benefit (reduction in relapse frequency from baseline [before treatment] or a decrease in NMOSD-related hospitalizations)
   2. You will NOT use Uplizna concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

C. If you have generalized myasthenia gravis, renewal also requires:
   1. You have shown a clinical benefit compared to baseline according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   2. You will NOT use Uplizna concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]) or complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]) for the treatment of generalized myasthenia gravis (a chronic autoimmune disorder)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Uplizna.

REFERENCES

Uplizna [Prescribing Information]. Dublin, Ireland: Amgen, Inc.; December 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB	REMICADE, INFLIXIMAB	18747		GPI-10 (5250504000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is currently using or has a contraindication to methotrexate
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL or GPI-10.**
If no, continue to #4.

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Taltz (ixekizumab)
  - Sotyktu (deucravacitinib)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Icotyde (icotrokinra)

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, continue to #6.
  If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

  If yes, **approve for 6 months by HICL or GPI-10.**
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Does the patient meet **ONE** of the following criteria?
    - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
      - Adalimumab-ryvk/adalimumab-aaty
      - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
      - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      - Skyrizi (risankizumab-rzaa)
      - Tremfya (guselkumab)
      - Omvoh (mirikizumab-mrkz)
      - Adalimumab-ryvk/adalimumab-aaty
      - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
      - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10.**
    If no, do not approve.
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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

E. If you have severe plaque psoriasis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
4. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Tremfya (guselkumab)
   c. Skyrizi (risankizumab-rzaa)
   d. Enbrel (etanercept)
   e. Otezla (apremilast)
   f. Taltz (ixekizumab)
   g. Sotyktu (deucravacitinib)
   h. Bimzelx (bimekizumab-bkzx)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Icotyde (icotrokinra)
6. You meet ONE of the following:
   a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB

INITIAL CRITERIA (CONTINUED)

G. If you have moderate to severe ulcerative colitis, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient is currently using or has a contraindication to methotrexate
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Taltz (ixekizumab)
  - Sotyktu (deucravacitinib)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Icotyde (icotrokinra)

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 12 months by HICL or GPI-10.**
  If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

  If yes, continue to #7.
  If no, continue to #8.

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

7. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

9. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Severe plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   (Renewal denial text continued on next page)

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You are currently using or have a contraindication to (harmful for you to use) methotrexate
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
4. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, renewal also requires:

1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

E. If you have severe plaque psoriasis, renewal also requires:

1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Tremfya (guselkumab)
   c. Skyrizi (risankizumab-rzaa)
   d. Enbrel (etanercept)
   e. Otezla (apremilast)
   f. Taltz (ixekizumab)
   g. Sotyktu (deucravacitinib)
   h. Bimzelx (bimekizumab-bkzx)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Icotyde (icotrokinra)

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, renewal also requires:

1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
2. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB

RENEWAL CRITERIA (CONTINUED)

G. If you have moderate to severe ulcerative colitis, renewal also requires:

1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
2. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Remicade.

REFERENCES

Remicade [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; February 2025.

Created: 02/03
Effective: 09/09/26 Client Approval: 09/26 DMC Approval: 09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-ABDA	RENFLEXIS	44432		GPI-10 (5250504010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is currently using or has a contraindication to methotrexate
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL or GPI-10.**
If no, continue to #4.

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
- Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Taltz (ixekizumab)
  - Sotyktu (deucravacitinib)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Icotyde (icotrokinra)

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, continue to #6.
  If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

  If yes, **approve for 6 months by HICL or GPI-10.**
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Does the patient meet **ONE** of the following criteria?
    - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
      - Adalimumab-ryvk/adalimumab-aaty
      - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
      - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      - Skyrizi (risankizumab-rzaa)
      - Tremfya (guselkumab)
      - Omvoh (mirikizumab-mrkz)
      - Adalimumab-ryvk/adalimumab-aaty
      - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
      - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10.**
    If no, do not approve.
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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   6. You meet ONE of the following:
      a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INITIAL CRITERIA (CONTINUED)

b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

E. If you have severe plaque psoriasis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
4. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Tremfya (guselkumab)
   c. Skyrizi (risankizumab-rzaa)
   d. Enbrel (etanercept)
   e. Otezla (apremilast)
   f. Taltz (ixekizumab)
   g. Sotyktu (deucravacitinib)
   h. Bimzelx (bimekizumab-bkzx)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Icotyde (icotrokinra)
6. You meet ONE of the following:
   a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

G. If you have moderate to severe ulcerative colitis, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient is currently using or has a contraindication to methotrexate
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
- Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - o Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - o Tremfya (guselkumab)
  - o Skyrizi (risankizumab-rzaa)
  - o Enbrel (etanercept)
  - o Otezla (apremilast)
  - o Taltz (ixekizumab)
  - o Sotyktu (deucravacitinib)
  - o Bimzelx (bimekizumab-bkzx)
  - 0 Adalimumab-ryvk/adalimumab-aaty
  - 0 Icotyde (icotrokinra)

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 12 months by HICL or GPI-10.**
  If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #7.
   If no, continue to #8.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

7. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Renflexis will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

9. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-ABDA (Renflexis)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Severe plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   (Renewal denial text continued on next page)

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You are currently using or have a contraindication to (harmful for you to use) methotrexate
3. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
4. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RENEWAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, renewal also requires:

1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

E. If you have severe plaque psoriasis, renewal also requires:

1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
2. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Tremfya (guselkumab)
   c. Skyrizi (risankizumab-rzaa)
   d. Enbrel (etanercept)
   e. Otezla (apremilast)
   f. Taltz (ixekizumab)
   g. Sotyktu (deucravacitinib)
   h. Bimzelx (bimekizumab-bkzx)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Icotyde (icotrokinra)

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, renewal also requires:

1. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
2. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

G. If you have moderate to severe ulcerative colitis, renewal also requires:

1. You will NOT use Renflexis concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
2. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Renflexis and Remicade.

REFERENCES

Renflexis [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc; January 2023.
Remicade [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; February 2025.

Created: 07/17
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-AXXQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-AXXQ	AVSOLA	46242		GPI-10 (5250504013)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is currently using or has a contraindication to methotrexate
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL or GPI-10.**
If no, continue to #4.

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
- Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Taltz (ixekizumab)
  - Sotyktu (deucravacitinib)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Icotyde (icotrokinra)

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, continue to #6.
  If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

  If yes, **approve for 6 months by HICL or GPI-10.**
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Does the patient meet **ONE** of the following criteria?
    - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
      - Adalimumab-ryvk/adalimumab-aaty
      - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
      - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      - Skyrizi (risankizumab-rzaa)
      - Tremfya (guselkumab)
      - Omvoh (mirikizumab-mrkz)
      - Adalimumab-ryvk/adalimumab-aaty
      - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
      - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

E. If you have severe plaque psoriasis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
4. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Tremfya (guselkumab)
   c. Skyrizi (risankizumab-rzaa)
   d. Enbrel (etanercept)
   e. Otezla (apremilast)
   f. Taltz (ixekizumab)
   g. Sotyktu (deucravacitinib)
   h. Bimzelx (bimekizumab-bkzx)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Icotyde (icotrokinra)
6. You meet ONE of the following:
   a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB-AXXQ

INITIAL CRITERIA (CONTINUED)

G. If you have moderate to severe ulcerative colitis, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient is currently using or has a contraindication to methotrexate
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #4.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
- Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - o Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - o Tremfya (guselkumab)
  - o Skyrizi (risankizumab-rzaa)
  - o Enbrel (etanercept)
  - o Otezla (apremilast)
  - o Taltz (ixekizumab)
  - 0 Sotyktu (deucravacitinib)
  - o Bimzelx (bimekizumab-bkzx)
  - 0 Adalimumab-ryvk/adalimumab-aaty
  - 0 Icotyde (icotrokinra)

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 12 months by HICL or GPI-10.**
  If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #7.
   If no, continue to #8.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

7. Does the patient meet ONE of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Avsola will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

9. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Severe plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   (Renewal denial text continued on next page)

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You are currently using or have a contraindication to (harmful for you to use) methotrexate
3. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
4. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RENEWAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, renewal also requires:

1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

E. If you have severe plaque psoriasis, renewal also requires:

1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
2. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Tremfya (guselkumab)
   c. Skyrizi (risankizumab-rzaa)
   d. Enbrel (etanercept)
   e. Otezla (apremilast)
   f. Taltz (ixekizumab)
   g. Sotyktu (deucravacitinib)
   h. Bimzelx (bimekizumab-bkzx)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Icotyde (icotrokinra)

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INFLIXIMAB-AXXQ

RENEWAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, renewal also requires:

1. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
2. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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RENEWAL CRITERIA (CONTINUED)

G. If you have moderate to severe ulcerative colitis, renewal also requires:

1. You will NOT use Avsola concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
2. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Avsola and Remicade.

REFERENCES

Avsola [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; September 2025.
Remicade [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; February 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-DYYB	INFLECTRA		40977	GPI-14 (52505040202120)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is currently using or has a contraindication to methotrexate
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID or GPI-14.**
If no, continue to #4.

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #5.

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a dermatologist
- The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
- Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Taltz (ixekizumab)
  - Sotyktu (deucravacitinib)
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty
  - Icotyde (icotrokinra)

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, continue to #6.
  If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
- The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
- The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
- The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

  If yes, **approve for 6 months by GPID or GPI-14.**
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Does the patient meet **ONE** of the following criteria?
    - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
      - Adalimumab-ryvk/adalimumab-aaty
      - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
      - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      - Skyrizi (risankizumab-rzaa)
      - Tremfya (guselkumab)
      - Omvoh (mirikizumab-mrkz)
      - Adalimumab-ryvk/adalimumab-aaty
      - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
      - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by GPID or GPI-14.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB-DYYB - IV (Inflectra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Severe plaque psoriasis (PsO: a type of skin condition)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
   4. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

E. If you have severe plaque psoriasis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
3. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
4. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Tremfya (guselkumab)
   c. Skyrizi (risankizumab-rzaa)
   d. Enbrel (etanercept)
   e. Otezla (apremilast)
   f. Taltz (ixekizumab)
   g. Sotyktu (deucravacitinib)
   h. Bimzelx (bimekizumab-bkzx)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Icotyde (icotrokinra)
6. You meet ONE of the following:
   a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, approval also requires:
1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB-DYYB - IV

INITIAL CRITERIA (CONTINUED)

G. If you have moderate to severe ulcerative colitis, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient is currently using or has a contraindication to methotrexate
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Taltz (ixekizumab)
  - Bimzelx (bimekizumab-bkzx)
  - Sotyktu (deucravacitinib)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 12 months by GPID or GPI-14.**
If no, continue to #4.

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #5.

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
- Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - o Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - o Tremfya (guselkumab)
  - o Skyrizi (risankizumab-rzaa)
  - o Enbrel (etanercept)
  - o Otezla (apremilast)
  - o Taltz (ixekizumab)
  - o Sotyktu (deucravacitinib)
  - o Bimzelx (bimekizumab-bkzx)
  - 0 Adalimumab-ryvk/adalimumab-aaty
  - 0 Icotyde (icotrokinra)

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 12 months by GPID or GPI-14.**
  If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
- Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

  If yes, continue to #7.
  If no, continue to #8.

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

7. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

8. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Inflectra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

9. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
     - Adalimumab-ryvk/adalimumab-aaty
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   - The patient is 18 years of age or older AND had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INFLIXIMAB-DYYB - IV (Inflectra)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Ankylosing spondylitis (AS: a type of joint condition)
      4. Severe plaque psoriasis (PsO: a type of skin condition)
      5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      6. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You are currently using or have a contraindication to (harmful for you to use) methotrexate
3. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
4. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RENEWAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   c. Otezla (apremilast)
   d. Tremfya (guselkumab)
   e. Skyrizi (risankizumab-rzaa)
   f. Taltz (ixekizumab)
   g. Bimzelx (bimekizumab-bkzx)
   h. Sotyktu (deucravacitinib)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   k. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, renewal also requires:

1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the BASDAI (Bath Ankylosing Spondylitis Disease Activity Index: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Adalimumab-ryvk/adalimumab-aaty
   e. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   f. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INFLIXIMAB-DYYB - IV

RENEWAL CRITERIA (CONTINUED)

E. If you have severe plaque psoriasis, renewal also requires:

1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis [a type of skin condition]) of at least 50 percent or more while on therapy
2. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Tremfya (guselkumab)
   c. Skyrizi (risankizumab-rzaa)
   d. Enbrel (etanercept)
   e. Otezla (apremilast)
   f. Taltz (ixekizumab)
   g. Sotyktu (deucravacitinib)
   h. Bimzelx (bimekizumab-bkzx)
   i. Adalimumab-ryvk/adalimumab-aaty
   j. Icotyde (icotrokinra)

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RENEWAL CRITERIA (CONTINUED)

F. If you have moderate to severe Crohn's disease, renewal also requires:

1. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
2. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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RENEWAL CRITERIA (CONTINUED)

G. If you have moderate to severe ulcerative colitis, renewal also requires:

1. You will NOT use Inflectra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
2. You meet ONE of the following:
   a. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Adalimumab-ryvk/adalimumab-aaty
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inflectra and Remicade.

REFERENCES

Inflectra [Prescribing Information]. New York, NY: Pfizer Labs, Inc.; September 2025.
Remicade [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; February 2025.

Created: 05/16
Effective: 09/09/26 Client Approval: 09/26 DMC Approval: 09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-DYYB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INFLIXIMAB-DYYB	ZYMFENTRA		55099 55098	GPI-14 (5250504020F530, 5250504020F830)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had prior treatment with an intravenous infliximab or infliximab biosimilar (e.g., Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 120mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB - SQ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient had prior treatment with an intravenous infliximab or infliximab biosimilar (e.g., Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 120mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-DYYB - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB-DYYB - SQ (Zymfentra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. If you have moderate to severe ulcerative colitis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   4. You meet ONE of the following:
      a. You had prior treatment with an intravenous (injection into the vein) infliximab or infliximab biosimilar (such as Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
      b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB-DYYB - SQ

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe Crohn's disease, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
4. You meet ONE of the following:
   a. You had prior treatment with an intravenous (injection into the vein) infliximab or infliximab biosimilar (such as Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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INFLIXIMAB-DYYB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had prior treatment with an intravenous infliximab or infliximab biosimilar (e.g., Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 120mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-DYYB - SQ

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Zymfentra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient had prior treatment with an intravenous infliximab or infliximab biosimilar (e.g., Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 120mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #2 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INFLIXIMAB-DYYB - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INFLIXIMAB-DYYB - SQ (Zymfentra)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. If you have moderate to severe ulcerative colitis, renewal also requires:
   1. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
   2. You meet ONE of the following:
      a. You had prior treatment with an intravenous (injection into the vein) infliximab or infliximab biosimilar (such as Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
      b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Skyrizi (risankizumab-rzaa)
         iii. Tremfya (guselkumab)
         iv. Omvoh (mirikizumab-mrkz)
         v. Adalimumab-ryvk/adalimumab-aaty
         vi. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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INFLIXIMAB-DYYB - SQ

RENEWAL CRITERIA (CONTINUED)

C. If you have moderate to severe Crohn's disease, renewal also requires:

1. You will NOT use Zymfentra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
2. You meet ONE of the following:
   a. You had prior treatment with an intravenous (injection into the vein) infliximab or infliximab biosimilar (such as Remicade [infliximab], Renflexis [infliximab-abda], Avsola [infliximab-axxq], Inflectra [infliximab-dyyb])
   b. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      ii. Skyrizi (risankizumab-rzaa)
      iii. Tremfya (guselkumab)
      iv. Omvoh (mirikizumab-mrkz)
      v. Adalimumab-ryvk/adalimumab-aaty
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zymfentra.

REFERENCES

Zymfentra [Prescribing Information]. Jersey City, NJ: Celltrion USA, Inc.; May 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INGENOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INGENOL MEBUTATE	PICATO	38449		GPI-10 (9037803520)	

GUIDELINES FOR USE

Do not approve requests for Picato gel.

(NOTE: Picato discontinued due to safety concerns and increased risk of cancer.)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Picato.

Manufacturer provided FDA with notification of discontinuation in the manufacture of Picato. Discontinuation may be likely due to safety concerns; Picato is no longer authorized in the EU after concluding that Picato increases the risk of cancer.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 05/12
Client Approval: 08/21
P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INHALED INSULIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INSULIN REGULAR, HUMAN	AFREZZA	00768		GPI-10 (2710401000)	BRAND= AFREZZA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient meet **ONE** of the following criteria?
   - The patient has chronic lung disease (i.e., asthma or chronic obstructive pulmonary disease)
   - The patient has active lung cancer
   - The patient is currently in diabetic ketoacidosis
   - The patient smokes or has quit smoking within the past 6 months

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of type 1 diabetes mellitus (ICD-10 Group E10) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a baseline spirometry performed to measure FEV1
   - The patient is concurrently using a long-acting insulin (e.g., Toujeo, Tresiba, Semglee)
   - The patient had a trial of ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

   If no, continue to #3.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E11, E13) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a baseline spirometry performed to measure FEV1
   - The patient had a trial of ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev
   - The prescriber has indicated that the patient is physically unable to or unwilling to administer injectable insulin

   If yes, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Type 1 diabetes mellitus (a disorder with high blood sugar)
      2. Type 2 diabetes mellitus (a disorder with high blood sugar)

   B. If you have type 1 diabetes mellitus, approval also requires:
      1. You are 6 years of age or older
      2. You had a baseline spirometry (a type of breathing test) to measure forced expiratory volume (FEV1: amount of air exhaled in one second)
      3. Afrezza will be used concurrently (at the same time) with a long-acting insulin (such as Toujeo, Tresiba, Semglee)
      4. You have tried ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev

   (Initial denial text continued on next page)

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

C. If you have type 2 diabetes mellitus, approval also requires:

1. You are 6 years of age or older
2. You had a baseline spirometry (a type of breathing test) to measure forced expiratory volume (FEV1: amount of air exhaled in one second)
3. You have tried ONE of the following preferred rapid-acting insulins: insulin lispro (Humalog), Lyumjev
4. Your prescriber has indicated that you are physically unable to or unwilling to use injectable insulin

NOTE: Afrezza will NOT be approved if you have any of the following conditions: chronic lung disease (type of long-term lung disease), active lung cancer, currently in diabetic ketoacidosis (condition where body breaks down fat too fast), you are currently smoking or you quit smoking within the past 6 months.

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INHALED INSULIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of type 1 diabetes mellitus (ICD-10 Group E10) **AND** is currently on a long-acting insulin (e.g., Toujeo, Tresiba, Semglee)?

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E11, E13)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Was follow-up spirometry to measure FEV1 performed after 6 months of treatment and then annually thereafter?

   If yes, continue to #4.
   If no, **approve for 1 month by GPID or GPI-14 (to allow for follow-up spirometry evaluation) with the following quantity limits:**
   - **90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
   - **90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
   - **90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
   - **30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
   - **60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

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INHALED INSULIN

RENEWAL CRITERIA (CONTINUED)

4. Has the patient's FEV1 declined by 20% or more from baseline?

If yes, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, **approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**

- **90-4 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
- **90-8 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
- **90-12 Unit Cartridges: #180 cartridges (2 kits) per 28 days.**
- **90-4 Unit + 90-8 Unit Titration pack: #180 cartridges (1 kit) per 28 days.**
- **90-8 Unit + 90-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**
- **30-4 Unit + 60-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
- **60-4 Unit + 30-8 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
- **60-8 Unit + 30-12 Unit Cartridges: #360 cartridges (4 kits) per 28 days.**
- **60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges: #180 cartridges (1 kit) per 28 days.**

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Type 1 diabetes mellitus (a disorder with high blood sugar)
   2. Type 2 diabetes mellitus (a disorder with high blood sugar)

B. If you have type 1 diabetes, renewal also requires:
   1. You have had a follow up spirometry (a type of breathing test) to measure your forced expiratory volume (FEV1: amount of air exhaled in one second) after 6 months of treatment and then annually (every year)
   2. Your FEV1 has NOT declined by 20 percent or more from baseline (before treatment)
   3. Afrezza will be used concurrently (at the same time) with a long-acting insulin (such as Toujeo, Tresiba, Semglee)

C. If you have type 2 diabetes, renewal also requires:
   1. You have had a follow up spirometry (a type of breathing test) to measure your forced expiratory volume (FEV1: amount of air exhaled in one second) after 6 months of treatment and then annually (every year)
   2. Your FEV1 has NOT declined by 20 percent or more from baseline (before treatment)

(Renewal denial text continued on next page)

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INHALED INSULIN

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Afrezza.

REFERENCES
Afrezza [Prescribing Information]. Danbury, CT: Mannkind Corporation; May 2026.

Created: 02/15
Effective: 06/24/26 Client Approval: 06/26 DMC Approval: 06/16/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTERSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INOTERSEN SODIUM	TEGSEDI	45353		GPI-10 (6270104010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   - The patient is ambulatory (i.e., Familial Amyloid Polyneuropathy [FAP] stage 1 - 2 or Polyneuropathy Disability [PND] Stage I - IIIb polyneuropathy)
   - Tegsedi will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])
   - The patient had a trial of or contraindication to the preferred agent: Amvuttra (vutrisiran)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the hATTR diagnosis confirmed by **ONE** of the following?
   - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
   - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INOTERSEN

INTIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
D. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
E. You will NOT use Tegsedi concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])
F. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Amvuttra
G. Your diagnosis is confirmed by ONE of the following:
    1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
    2. DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTERSEN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient has NOT progressed to Familial Amyloid Polyneuropathy (FAP) stage 3 or Polyneuropathy Disability (PND) Stage IV polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   - Tegsedi will NOT be used concurrently with other hATTR-PN agents (e.g. Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for renewal:
   A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
   B. You have NOT progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 OR Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage IV polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
   C. You will NOT use Tegsedi concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Amvuttra [vutrisiran], Onpattro [patisiran])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tegsedi.

REFERENCES

Tegsedi [Prescribing Information]. Waltham, MA: Sobi, Inc.; January 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 10/18
Client Approval: 05/24
P&T Approval: 04/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTUZUMAB OZOGAMICIN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INOTUZUMAB OZOGAMICIN	BESPONSA	44438		GPI-10 (2135264020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received 6 cycles of Besponsa treatment?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 6 months by HICL or GPI-10.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INOTUZUMAB OZOGAMICIN (Besponsa)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL: a type of blood cancer that has returned or did not respond to treatment)
   B. You are 1 year of age or older
   C. You have NOT previously received 6 cycles of Besponsa

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Besponsa.

REFERENCES

Besponsa [Prescribing Information]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; March 2024.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTUZUMAB OZOGAMICIN (NSA)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 08/17
Client Approval: 03/24
P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INSULIN DEVICES

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INSULIN INFUSION DISPOSABLE PUMP, INSULIN INFUSION SET/CARTRIDGE, INSULIN PUMP/CART/SET/SYR/NEED	MODD1 PATIENT WELCOME KIT, PIVOT INSULIN PUMP STARTER KIT	49840		GPI-10 (9720103050)	BRAND = MODD1, PIVOT SUPPLY KIT, PIVOT INSULIN PUMP STARTER KIT
	MODD1 SUPPLY KIT, PIVOT SUPPLY KIT	49004			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of diabetes mellitus (type 1 or type 2) (ICD-10 Groups E08, E09, E10, E11, E13) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested device is prescribed by or in consultation with an endocrinologist
   - The patient has completed a comprehensive diabetes education program within the preceding 24 months
   - The patient follows a maintenance program of at least 3 injections of insulin per day and has required frequent self-adjustments of insulin dose for the past 6 months
   - The patient has required glucose self-testing of at least 4 times per day on average in the preceding 2 months
   - The patient had a trial of ONE of the following preferred devices: CeQur, Omnipod 5, Omnipod DASH, V-Go, Twiist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INSULIN DEVICES

INITIAL CRITERIA (CONTINUED)

2. Is the patient on a multiple daily insulin injection regimen and meets **ONE** of the following criteria?
   - The patient has a glycosylated hemoglobin level (HbA1c) that is greater than 7%
   - The patient has a history of recurring hypoglycemia
   - The patient has wide fluctuations in blood glucose before mealtime
   - The patient experiences the dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dL
   - The patient has a history of severe glycemic excursions (sudden spikes in blood sugar levels)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for more than 10 cartridges per month?

   If yes, continue to #4.
   If no, **approve for 12 months by NDC for ALL of the following:**
   - **MODD1 Patient Welcome Kit: #4 per year.**
   - **MODD1 Supply Kit: #40 per 30 days.**
   - **Pivot Insulin Pump Starter kit.**
   - **Pivot Supply Kit.**

4. Is the patient using more than 300 units of insulin per 72 hours?

   If yes, **approve for 12 months by NDC for ALL of the following:**
   - **MODD1 Patient Welcome Kit: #4 per year.**
   - **MODD1 Supply Kit: Approve the requested quantity per 30 days.**
   - **Pivot Insulin Pump Starter kit.**
   - **Pivot Supply Kit: Approve the requested quantity per 30 days (Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   NOTE: Enter proactive PAs for 12 months by NDC for ALL of the following:
   - **MODD1 Patient Welcome Kit: #4 per year.**
   - **MODD1 Supply Kit: #40 per 30 days.**
   - **Pivot Insulin Pump Starter kit.**
   - **Pivot Supply Kit.**

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INSULIN DEVICES

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INSULIN DEVICES (MODD1, Pivot)** requires the following rule(s) be met for approval:

A. You have diabetes mellitus (type 1 or type 2) (a disorder with high blood sugar)
B. You are 18 years of age or older
C. The requested device is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. You have completed a comprehensive diabetes education program within the previous 24 months
E. You follow a maintenance program of at least 3 injections of insulin per day and have required frequent self-adjustments of your insulin dose for the past 6 months
F. You have required glucose self-testing of at least 4 times per day on average in the previous 2 months
G. You have tried ONE of the following preferred devices: CeQur, Omnipod 5, Omnipod DASH, V-Go, Twiist
H. You are on a multiple daily insulin injection regimen and meet ONE of the following:
    1. You have a glycosylated hemoglobin level (HbA1c: a type of lab test) that is greater than 7%
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations (variations) in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)
I. If you are requesting more than 10 cartridges per month, approval also requires:
    1. You are using more than 300 units of insulin per 72 hours

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INSULIN DEVICES

RENEWAL CRITERIA

1. Does the patient have a diagnosis of diabetes mellitus (type 1 or type 2) (ICD-10 Groups E08, E09, E10, E11, E13) **AND** meet the following criterion?
   - The patient has shown a positive response to therapy
   - The patient is adherent to physician follow-up visits

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for more than 10 cartridges per month?

   If yes, continue to #3.
   If no, **approve for 12 months by NDC for ALL of the following:**
   - **MODD1 Patient Welcome Kit: #4 per year.**
   - **MODD1 Supply Kit: #40 per 30 days.**
   - **Pivot Insulin Pump Starter kit.**
   - **Pivot Supply Kit.**

3. Is the patient using more than 300 units of insulin per 72 hours?

   If yes, **approve for 12 months by NDC for ALL of the following:**
   - **MODD1 Patient Welcome Kit: #4 per year.**
   - **MODD1 Supply Kit: Approve the requested quantity per 30 days.**
   - **Pivot Insulin Pump Starter kit.**
   - **Pivot Supply Kit: Approve the requested quantity per 30 days (Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   NOTE: Enter proactive PAs for 12 months by NDC for ALL of the following:
   - **MODD1 Patient Welcome Kit: #4 per year.**
   - **MODD1 Supply Kit: #40 per 30 days.**
   - **Pivot Insulin Pump Starter kit.**
   - **Pivot Supply Kit.**

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INSULIN DEVICES

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INSULIN DEVICES (MODD1, Pivot)** requires the following rule(s) be met for renewal:

A. You have diabetes mellitus (type 1 or type 2) (a disorder with high blood sugar)
B. You have shown a positive response to therapy
C. You are adherent (keeping up with) your doctor follow-up visits
D. If you are requesting more than 10 cartridges per month, approval also requires:
   1. You are using more than 300 units of insulin per 72 hours

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for MODD1 and Pivot.

REFERENCES

MODD1. Modular Medical, Inc. Available at: https://www.modularmedical.com/modd1. [Accessed January 23, 2026]
PivotTM Insulin Delivery System. Modular Medical, Inc. Availabe at: pivotpump.com [Accessed July 15, 2026].

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INSULIN PUMPS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUBCUTANEOUS INSULIN PUMP	T:SLIM X2, T:SLIM X2 CONTROL-IQ, T:SLIM X2 WITH BASAL-IQ, TANDEM T:SLIM STARTER KIT, TANDEM MOBI SYSTEM, MINIMED 670G, MINIMED 770G, MINIMED 780G, MINIMED 630G, ILET INSULIN PUMP	35487		GPI-10 (9720103000)	
INSULIN INFUSION PUMP	MINIMED FLEX				

GUIDELINES FOR USE

1. Is the claim rejecting for the following POS message: "***Coverage of this product should be provided through medical benefit, available manufacturer programs, or patient assistance programs"*****?**

If yes, guideline does not apply.
If no, continue to #2.

2. Does the patient meet **ALL** of the following criteria?
   - The insulin pump is prescribed by or in consultation with an endocrinologist
   - The patient has completed a comprehensive diabetes education program within the preceding 24 months
   - The patient follows a maintenance program of at least 3 injections of insulin per day and has required frequent self-adjustments of insulin dose for the past 6 months
   - The patient has required glucose self-testing at least 4 times per day on average in the preceding 2 months
   - The patient has NOT received an insulin pump within the last 4 years (Exception: pump is malfunctioning, not repairable, and not under warranty)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria while on a multiple daily insulin injection regimen?
   - The patient's glycosylated hemoglobin level (HbA1c) is greater than 7%
   - The patient has a history of recurring hypoglycemia
   - The patient has wide fluctuations in blood glucose before mealtime
   - The patient experiences the dawn phenomenon with fasting blood glucose levels frequently exceeding 200 mg/dL
   - The patient has a history of severe glycemic excursions (sudden spikes in blood sugar levels)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for T:Slim X2, Tandem T:Slim Starter Kit (T:Slim X2 Starter 7.10), or Tandem Mobi **AND** the patient meets the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, continue to #5.

5. Is the request for T:Slim X2 with Basal-IQ **AND** the patient meets the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, continue to #6.

6. Is the request for T:Slim X2 with Control-IQ?

   If yes, continue to #7.
   If no, continue to #9.

7. Does the patient have a diagnosis of type 1 diabetes mellitus **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, continue to #8.

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INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have a diagnosis of type 2 diabetes mellitus **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Is the request for MiniMed 670G and the patient meets **ALL** of the following criteria?
   - The patient has a diagnosis of type 1 diabetes mellitus
   - The patient is 7 years of age or older

   If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
   If no, continue to #10.

10. Is the request for MiniMed 770G and the patient meets **ALL** of the following criteria?
    - The patient has a diagnosis of type 1 diabetes mellitus
    - The patient is 2 years of age or older

    If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
    If no, continue to #11.

11. Is the request for MiniMed 780G and the patient meets **ALL** of the following criteria?
    - The patient has a diagnosis of type 1 diabetes mellitus
    - The patient is 7 years of age or older

    If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
    If no, continue to #12.

12. Is the request for MiniMed 630G and the patient meets **ALL** of the following criteria?
    - The patient has a diagnosis of type 1 diabetes mellitus
    - The patient is 14 years of age or older

    If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
    If no, continue to #13.

13. Is the request for iLet Bionic Pancreas insulin pump and the patient meets **ALL** of the following criteria?
    - The patient has a diagnosis of type 1 diabetes mellitus
    - The patient is 6 years of age or older

    If yes, **approve for 1 month by NDC with a quantity limit of #1 fill.**
    If no, continue to #14.

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INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

14. Is the request for MiniMed Flex starter kit (infusion pump) and the patient meets **ONE** of the following criteria?
    - The patient has a diagnosis of type 1 diabetes mellitus AND is 7 years of age and older
    - The patient has a diagnosis of type 2 diabetes mellitus, is 18 years of age and older, AND requires insulin

    If yes, **approve for 1 month for all NDCs with a quantity limit of #1 fill.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **INSULIN PUMPS** requires the following rule(s) be met for approval:
    A. The requested insulin pump is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
    B. You have completed a comprehensive diabetes education program within the previous 24 months
    C. You follow a maintenance program of at least 3 injections of insulin per day and have required frequent self-adjustments of your insulin dose for the past 6 months
    D. You have required glucose self-testing at least 4 times per day on average in the previous 2 months
    E. You have NOT received an insulin pump within the last 4 years (Exception: your pump is malfunctioning, not repairable, and not under warranty)
    F. You are on a multiple daily insulin injection regimen and meet ONE of the following:
        1. You have a glycosylated hemoglobin level (HbA1c: a type of lab test) greater than 7 percent
        2. You have a history of recurring hypoglycemia (low blood sugar)
        3. You have wide fluctuations in blood sugar before mealtime
        4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
        5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)

    (Denial text continued on next page)

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INSULIN PUMPS

GUIDELINES FOR USE (CONTINUED)

G. If you are requesting the T:Slim X2, Tandem T:Slim Starter Kit (T:Slim X2 Starter 7.10), OR Tandem Mobi, approval also requires:
1. You are 2 years of age or older

H. If you are requesting the T:Slim X2 with Basal-IQ, approval also requires:
1. You are 6 years of age or older

I. If you are requesting the T:Slim X2 with Control-IQ, approval also requires ONE of the following:
1. You have type 1 diabetes mellitus (a disorder with high blood sugar) AND you are 2 years of age or older
2. You have type 2 diabetes mellitus (a disorder with high blood sugar) AND you are 18 years of age or older

J. If you are requesting the MiniMed 670G, approval also requires:
1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
2. You are 7 years of age or older

K. If you are requesting the MiniMed 770G, approval also requires:
1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
2. You are 2 years of age or older

L. If you are requesting the MiniMed 780G, approval also requires:
1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
2. You are 7 years of age or older

M. If you are requesting the MiniMed 630G, approval also requires:
1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
2. You are 14 years of age or older

N. If you are requesting the iLet Bionic Pancreas insulin pump, approval also requires:
1. You have type 1 diabetes mellitus (a disorder with high blood sugar)
2. You are 6 years of age or older

O. If you are requesting the MiniMed Flex starter kit (infusion pump), approval also requires ONE of the following:
1. You have type 1 diabetes mellitus (a disorder with high blood sugar) AND are 7 years of age and older
2. You have type 2 diabetes mellitus (a disorder with high blood sugar), are 18 years of age and older, AND require insulin

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INSULIN PUMPS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related insulin pumps.

REFERENCES

T:Slim X2 Insulin Pump. Tandem Diabetes Care. Important Safety Information. Available at: https://www.tandemdiabetes.com/products/insulin-pumps/tslim-x2-insulin-pump
Tandem Mobi Insulin Pump. Tandem Diabetes Care. Important Safety Information. Available at: https://www.tandemdiabetes.com/products/insulin-pumps/tandem-mobi
MiniMed 670G System. Medtronic. Important Safety Information. Available at: https://www.medtronicdiabetes.com/important-safety-information#minimed-670g
MiniMed 770G System. Medtronic. Important Safety Information. Available at: https://www.medtronicdiabetes.com/important-safety-information#minimed-770g
MiniMed 780G System. Medtronic. Important Safety Information. Available at: https://www.medtronicdiabetes.com/important-safety-information#minimed-780g
MiniMed 630G System. Medtronic. Important Safety Information. Available at: https://www.medtronicdiabetes.com/important-safety-information#minimed-630g
MiniMed Flex System. Medtronic. Important Safety Information. Available at: https://www.minimed.com/en-us/important-safety-information.
iLet Bionic Pancreas. Beta Bionics. Important Safety Information. Available at: Safety Information - Beta Bionics

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON ALFA-2B,RECOMB.	INTRON A	04528		GPI-10 (2170006020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Hairy cell leukemia (ICD-10 Group C91.4)
   - Condylomata acuminata (ICD-10 A63.0)
   - AIDS-related Kaposi's sarcoma (ICD-10 C46.9)
   - Chronic hepatitis B (ICD-10 B18.0, B18.1)
   - Non-Hodgkin's lymphoma (ICD-10 Group C85)
   - Malignant melanoma (ICD-10 Group C43)
   - Chronic phase, Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) (ICD-10 Group C92.1) patients who are minimally treated (within 1 year of diagnosis)
   - Follicular lymphoma (ICD-10 Group C82)
   - Angioblastoma
   - Carcinoid tumor (ICD-10 C7A.00)
   - Chronic myeloid leukemia (ICD-10 C92.1, C92.2)
   - Laryngeal papillomatosis (ICD-10 D14.1)
   - Multiple myeloma (ICD-10 Group C90.0)
   - Neoplasm of conjunctiva-neoplasm of cornea (ICD-10 C69.00)
   - Ovarian cancer (ICD-10 C56.9)
   - Polycythemia vera (ICD-10 D45)
   - Renal cell carcinoma (ICD-10 Groups C64, C65)
   - Skin cancer (ICD-10 C44.90)
   - Thrombocytosis (ICD-10 D75.83)
   - Vulvar vestibulitis (ICD-10 N94.810)

   If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
   If no, continue to #2.

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of chronic hepatitis C (ICD-10 B18.2) and meet **ALL** of the following criteria?
   - The patient has genotype 1, 2, 3, 4, 5, or 6 infection
   - Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., hepatologist)
   - The patient has a detectable pretreatment HCV RNA level/viral load of 50 IU/mL or higher
   - Intron A will be used with ribavirin or the patient has a contraindication to ribavirin
   - The patient had a trial of or contraindication to one clinical standard of care agent: peginterferon alfa-2a or peginterferon alfa-2b

   If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Chronic hepatitis C (a type of liver infection)
      2. Hairy cell leukemia (bone marrow cancer that makes too many white blood cells)
      3. Condylomata acuminate (genital warts)
      4. AIDS (acquired immunodeficiency syndrome)-related Kaposi's sarcoma (cancer in those with weak immune system that causes tumors of lymph nodes/skin)
      5. Chronic hepatitis B (a type of liver infection)
      6. Non-Hodgkin's lymphoma (a type of blood cancer)
      7. Malignant melanoma (a type of skin cancer)
      8. Chronic phase, Philadelphia chromosome (type of abnormal gene) positive chronic myelogenous leukemia (type of blood cancer) who are minimally treated (within 1 year of diagnosis)
      9. Follicular lymphoma (a type of blood cancer)
      10. Angioblastoma (certain blood-vessel tumors of the brain)
      11. Carcinoid tumor (a type of slow growing cancerous tumor)
      12. Chronic myeloid leukemia (a type of blood cancer)
      13. Laryngeal papillomatosis (tumors form along the pathways for breathing/digestion)

   (Initial denial text continued on next page)

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

14. Multiple myeloma (a type of blood cancer)
15. Neoplasm of conjunctiva-neoplasm of cornea (eye tumors)
16. Ovarian cancer (a type of reproductive system cancer)
17. Polycythemia vera (a type of blood cancer)
18. Renal cell carcinoma (a type of kidney cancer)
19. Skin cancer
20. Thrombocytosis (your body makes too many platelets)
21. Vulvar vestibulitis (type of pain around the female sex organ called the vulva)

B. If you have chronic hepatitis C, approval also requires:

1. You have genotype 1, 2, 3, 4, 5, or 6 infection (types of hepatitis C virus)
2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
3. You have a detectable pretreatment HCV (hepatitis C virus) RNA level/viral load (amount of virus in your blood) of 50 IU/mL or higher
4. Intron A will be used with ribavirin or you have a contraindication to (harmful for you to use) ribavirin
5. You had a trial of or contraindication to one clinical standard of care medication: peginterferon alfa-2a or peginterferon alfa-2b

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON ALFA-2B

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic hepatitis C (ICD-10 B18.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., hepatologist)

   If yes, continue to #2.
   If no, **approve by HICL or GPI-10 for 24 weeks (6 months).**

2. Has the patient already received 24 weeks or more of interferon during this treatment?

   If yes, continue to #3.
   If no, **approve by HICL or GPI-10 for 24 weeks (6 months).**

3. Is the patient's HCV RNA undetectable (less than 50 IU/mL) at 24 weeks?

   If yes, **approve by HICL or GPI-10 for 24 weeks (6 months).**
   If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for renewal:

A. The request is for continuation of current therapy or renewal with Intron A therapy

B. If you have chronic hepatitis C (type of liver infection), renewal also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
2. If you already received 24 weeks or more of interferon treatment, your HCV (hepatitis C virus) RNA level (amount of virus in your blood) is undetectable (less than 50 IU/mL) at 24 weeks

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON ALFA-2B

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Intron A.

REFERENCES

Intron A [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; November 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS - AVONEX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1A	AVONEX, AVONEX PEN	11253		GPI-10 (6240306045)	MEDI-SPAN: BRAND = AVONEX, AVONEX PEN, AVONEX PREFILLED

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Avonex: #1 kit per 28 days or #2mL (4 syringes) per 28 days.**
   - **Avonex Pen: #1 pen injector kit per 28 days or #2mL (4 pens) per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - AVONEX** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Avonex.

REFERENCES
Avonex [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2023.

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Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS - BETASERON

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1B	BETASERON	08537		GPI-10 (6240306050)	BRAND = BETASERON

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months for all NDCs of Betaseron for #14 (vials or kits) per 28 days.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - BETASERON** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Betaseron.

REFERENCES
Betaseron [Prescribing Information]. Whippany, NJ: Bayer; July 2023.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS - EXTAVIA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1B	EXTAVIA	08537		GPI-10 (6240306050)	BRAND = EXTAVIA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Avonex (interferon beta-1a), Copaxone/Glatiramer/Glatopa (glatiramer), Plegridy (peginterferon beta- 1a), Rebif (interferon beta-1a/albumin), teriflunomide (Aubagio)

   If yes, **approve Extavia for 12 months for all NDCs (FDB or MediSpan) with a quantity limit of #14 vials or kits per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - EXTAVIA** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Avonex (interferon beta-1a), Copaxone/Glatiramer/Glatopa (glatiramer), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a/albumin), teriflunomide (Aubagio)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Extavia.

REFERENCES

Extavia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2023.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS - PLEGRIDY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGINTERFERON BETA-1A	PLEGRIDY, PLEGRIDY PEN	41331		GPI-10 (6240307530)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Plegridy Starter Pack Pen/Syringe: approve for 1 month with a quantity limit of #1mL (2 prefilled pens or syringes).**
   - **SECOND APPROVAL: Plegridy 125mcg Pen/Syringe: approve for 11 months (total approval duration of 12 months) with a quantity limit of #1mL (2 prefilled pens or syringes) per 28 days. (Please enter start date of 3 weeks AFTER the START date of the first approval).**

   SUBSEQUENT REQUESTS:
   - **Plegridy 125mcg Pen/Syringe: approve for 12 months with a quantity limit of #1mL (2 prefilled pens or syringes) per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - PLEGRIDY** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS - PLEGRIDY

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Plegridy.

REFERENCES

Plegridy [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2023.

Created: 10/22
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON FOR MS - REBIF

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON BETA-1A/ALBUMIN	REBIF, REBIF REBIDOSE	23353		GPI-10 (6240306045)	MEDI-SPAN: BRAND = REBIF%

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for a total of 12 months by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Rebif Titration Pack/Rebif Rebidose Titration Pack: approve for 1 month with a quantity limit of #4.2 mL (12 syringes) per 28 days.**
   - **SECOND APPROVAL: Rebif/Rebif Rebidose: approve for 11 months with a quantity limit of #6 mL (12 syringes) per 28 days. (Please enter start date of 3 weeks AFTER the START date of the first approval.).**

   SUBSEQUENT REQUESTS:
   - **Rebif/Rebif Rebidose: approve for 12 months with a quantity limit of #6 mL (12 syringes) per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON FOR MS - REBIF** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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INTERFERON FOR MS - REBIF

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rebif.

REFERENCES

Rebif [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; July 2023.

Created: 10/22
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON GAMMA-1B, RECOMB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON GAMMA-1B, RECOMB.	ACTIMMUNE	06068		GPI-10 (2170006070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist, infectious disease specialist, or immunologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of severe malignant osteopetrosis (SMO) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an endocrinologist or hematologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for approval:
   A. You have ONE of the following:
      1. Chronic granulomatous disease (CGD: a type of immune disorder)
      2. Severe malignant osteopetrosis (SMO: a type of bone condition)
   B. If you have chronic granulomatous disease, approval also requires:
      1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), infectious disease specialist (a doctor that specializes in treating infections), or immunologist (a type of immune system doctor)
   C. If you have severe malignant osteopetrosis, approval also requires:
      1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor) or hematologist (a type of blood doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON GAMMA-1B, RECOMB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) or severe malignant osteopetrosis (SMO) and meet **ALL** of the following criteria?
   - The patient has demonstrated clinical benefit compared to baseline (e.g., reduction in frequency and severity of serious infections)
   - The patient has NOT received hematopoietic cell transplantation

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for renewal:
   A. You have ONE of the following:
      1. Chronic granulomatous disease (CGD: a type of immune disorder)
      2. Severe malignant osteopetrosis (SMO: a type of bone condition)
   B. You have shown clinical benefit compared to baseline (such as reduction in frequency and severity of serious infections)
   C. You have NOT received hematopoietic cell transplantation (bone marrow transplant)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actimmune.

REFERENCES

Actimmune [Prescribing Information] Lake Forest, IL: Horizon Therapeutics USA, Inc., January 2020.

Created: 09/05
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IOBENGUANE IODINE 131 (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IOBENGUANE I 131	AZEDRA	25483		GPI-10 (2160003520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient requires systemic anticancer therapy
   - The tumors are iobenguane scan positive
   - The patient has **NOT** previously received 1 dosimetric dose and 2 therapeutic doses of Azedra

   If yes, **approve for 12 months by GPID or GPI-14 for all dosages with the following quantity limits:**
   - **Azedra Dosimetric: #1 vial per 12 months.**
   - **Azedra Therapeutic: #4 vials per 12 months.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IOBENGUANE IODINE 131 (Azedra)** requires the following rule(s) be met for approval:
   A. You have unresectable (cannot be removed completely through surgery), locally advanced or metastatic pheochromocytoma (type of tumor that releases hormones) or paraganglioma (type of tumors)
   B. You are 12 years of age or older
   C. You require systemic anticancer therapy (cancer treatment that travels in the blood throughout the entire body)
   D. The tumors are iobenguane scan positive (type of test that detects a tumor)
   E. You have **NOT** previously received 1 dosimetric dose (measurement of how much radiation dose is absorbed by the body) and 2 therapeutic doses of Azedra

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IOBENGUANE IODINE 131 (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Azedra.

REFERENCES

Azedra [Prescribing Information]. New York, NY: Progenics Pharmaceuticals, Inc. Pharmaceuticals Corporation. March 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/18
Client Approval: 04/20
P&T Approval: 10/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPILIMUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IPILIMUMAB	YERVOY	37503		GPI-10 (2135523200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Yervoy will be used as a single agent OR in combination with Opdivo (nivolumab)

   If yes, **approve for 4 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of cutaneous melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - Yervoy will be used for adjuvant treatment
   - There is pathologic involvement of regional lymph nodes of more than 1mm
   - The patient has undergone complete resection, including total lymphadenectomy

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
   - Yervoy will be used in combination with Opdivo (nivolumab)
   - The patient has intermediate or poor risk disease

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer (ICD-10 C19) and meet **ALL** the following criteria?
   - The patient is 12 years of age or older
   - Yervoy will be used in combination with Opdivo (nivolumab)
   - The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, continue to #5.

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IPILIMUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (ICD-10 C22.0) and meet **ONE** of the following criteria?
   - Yervoy will be used in combination with Opdivo (nivolumab) as first-line treatment
   - Yervoy will be used in combination with Opdivo (nivolumab), AND the patient has previously been treated with Nexavar (sorafenib)

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors express PD-L1 (at least 1%), as determined by an FDA-approved test
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations
   - Yervoy will be used in combination with Opdivo (nivolumab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient have a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations
   - Yervoy will be used in combination with Opdivo (nivolumab) and 2 cycles of platinum-doublet chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

8. Does the patient have a diagnosis of unresectable malignant pleural mesothelioma (ICD-10 C45.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Yervoy will be used in combination with Opdivo (nivolumab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

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IPILIMUMAB

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Yervoy will be used in combination with Opdivo (nivolumab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IPILIMUMAB (Yervoy)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
      2. Cutaneous melanoma (a type of skin cancer)
      3. Advanced renal cell carcinoma (a type of kidney cancer)
      4. Unresectable or metastatic colorectal cancer (type of digestive tract cancer that cannot be completely removed by surgery or has spread to other parts of the body)
      5. Unresectable or metastatic hepatocellular carcinoma (a type of liver cancer that cannot be completely removed by surgery or has spread to other parts of the body)
      6. Metastatic or recurrent non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body or has returned)
      7. Unresectable (cannot be removed by surgery) malignant pleural mesothelioma (a tumor of the tissue that has spread and lines the lungs, stomach, heart, and other organs)
      8. Unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC: a type of digestive cancer that cannot be removed by surgery or has spread to other parts of the body)

   B. If you have unresectable or metastatic melanoma, approval also requires:
      1. You are 12 years of age or older
      2. Yervoy will be used as a single medication OR in combination with Opdivo (nivolumab)

   C. If you have cutaneous melanoma, approval also requires:
      1. Yervoy will be used for adjuvant (add-on) treatment
      2. There is pathologic (disease) involvement of regional lymph nodes of more than 1mm
      3. You have undergone complete resection (surgery to completely remove cancer), including total lymphadenectomy (lymph glands are surgically removed)

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IPILIMUMAB

INITIAL CRITERIA (CONTINUED)

D. If you have advanced renal cell carcinoma, approval also requires:
1. Yervoy will be used in combination with Opdivo (nivolumab)
2. You have intermediate or poor risk disease

E. If you have unresectable or metastatic colorectal cancer, approval also requires:
1. You are 12 years of age or older
2. Yervoy will be used in combination with Opdivo (nivolumab)
3. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities)

F. If you have unresectable or metastatic hepatocellular carcinoma, approval also requires ONE of the following:
1. Yervoy will be used in combination with Opdivo (nivolumab) as first-line treatment
2. Yervoy will be used in combination with Opdivo (nivolumab), AND you have previously been treated with Nexavar (sorafenib)

G. If you have metastatic or recurrent non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of protein) genomic tumor aberrations (types of gene mutations)
3. You meet ONE of the following:
   a. **For metastatic NSCLC,** Yervoy will be used in combination with Opdivo (nivolumab) AND your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) (at least 1%), as determined by an FDA (Food and Drug Administration)-approved test
   b. **For metastatic or recurrent NSCLC,** Yervoy will be used in combination with Opdivo (nivolumab) and 2 cycles of platinum-doublet chemotherapy (type of cancer medication)

H. If you have unresectable malignant pleural mesothelioma, approval also requires:
1. You are 18 years of age or older
2. Yervoy will be used in combination with Opdivo (nivolumab)

I. If you have unresectable advanced or metastatic esophageal squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. Yervoy will be used in combination with Opdivo (nivolumab)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IPILIMUMAB

RENEWAL CRITERIA

NOTE: For the diagnoses of unresectable or metastatic melanoma, advanced renal cell carcinoma, unresectable or metastatic colorectal cancer, unresectable or metastatic hepatocellular carcinoma, metastatic/recurrent non-small cell lung cancer (NSCLC), unresectable malignant pleural mesothelioma, or unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of cutaneous melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - Yervoy will be used for adjuvant treatment
   - There is NO evidence of disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant metastasis)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IPILIMUMAB (Yervoy)** requires the following rule(s) be met for renewal:
   A. You have cutaneous melanoma (a type of skin cancer)
   B. Yervoy will be used for adjuvant (add-on) treatment
   C. You do NOT have any disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant metastasis [cancer has spread from original site])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yervoy.

REFERENCES

Yervoy [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; April 2025.

Created: 04/11
Effective: 05/12/25 Client Approval: 04/25 P&T Approval: 04/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IPTACOPAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IPTACOPAN HCL	FABHALTA	49336		GPI-10 (8580753520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient's diagnosis is confirmed by flow cytometry that shows PNH granulocyte clone size of at least 10 percent AND at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
   - Fabhalta will NOT be used concurrently with a C5 complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]) or Factor D inhibitor (e.g., Voydeya [danicopan])

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is at risk of rapid disease progression (e.g., urine protein-to-creatinine ratio [UPCR] of at least 1.5 g/g)
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a renal biopsy
   - The patient has an eGFR of at least 20 mL/min/1.73 m(2)
   - The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes

   If yes, **approve for 9 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

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IPTACOPAN

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of complement 3 glomerulopathy (C3G) (ICD-10 N00.A, N01.A, N02.A, N03.A, N04.A, N05.A, N06.A, N07.A, N00.6, N01.6, N02.6, N03.6, N04.6, N05.6, N06.6, N07.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a renal biopsy
   - The patient has a urine-protein creatine ratio (UPCR) of at least 1 g/g
   - The patient has an eGFR of at least 30mL/min/1.73m(2)
   - The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes
   - Fabhalta will NOT be used concurrently with another complement inhibitor (e.g., Empaveli [pegcetacoplan]) for the treatment of C3G

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IPTACOPAN (Fabhalta)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      2. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
      3. Complement 3 glomerulopathy (C3G: a type of kidney disease)

   B. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
      3. Your paroxysmal nocturnal hemoglobinuria (PNH) diagnosis is confirmed by flow cytometry (a type of lab test) that shows ALL of the following:
         a. You have a PNH granulocyte clone size of at least 10%
         b. You have at least 2 different GPI-protein deficiencies (a certain type of protein is missing, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell])
      4. You will NOT use Fabhalta concurrently (at the same time) with a C5 complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]) or Factor D inhibitor (such as Voydeya [danicopan])

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IPTACOPAN

INITIAL CRITERIA (CONTINUED)

C. If you have primary immunoglobulin A nephropathy, approval also requires:
1. You are 18 years of age or older
2. You are at risk of rapid disease progression (such as a urine protein-to-creatinine ratio [UPCR: a test that measures the amount of protein in urine] of at least 1.5 g/g)
3. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
4. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
5. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 20 mL/min/1.73 m(2)
6. You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes

D. If you have complement 3 glomerulopathy, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
3. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
4. You have a urine-protein creatine ratio (UPCR: a test that measures the amount of protein in urine) of at least 1g/g
5. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30mL/min/1.73m(2)
6. You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes
7. You will NOT use Fabhalta concurrently (at the same time) with another complement inhibitor (such as Empaveli [pegcetacoplan]) for the treatment of complement 3 glomerulopathy (a type of kidney disease)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IPTACOPAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline
   - Fabhalta will NOT be used concurrently with a C5 complement inhibitor (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (e.g., Empaveli [pegcetacoplan]) or Factor D inhibitor (e.g., Voydeya [danicopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ONE** of the following criteria?
   - The patient has had a reduction in proteinuria
   - The patient has improved or stable kidney function compared to baseline

   If yes, **approve for 9 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of complement 3 glomerulopathy (C3G) (ICD-10 N00.A, N01.A, N02.A, N03.A, N04.A, N05.A, N06.A, N07.A, N00.6, N01.6, N02.6, N03.6, N04.6, N05.6, N06.6, N07.6) and meet **ALL** of the following criteria?
   - The patient has improved or stable kidney function compared to baseline OR has a reduction in proteinuria
   - Fabhalta will NOT be used concurrently with another complement inhibitor (e.g., Empaveli [pegcetacoplan]) for the treatment of C3G

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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IPTACOPAN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IPTACOPAN (Fabhalta)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   2. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   3. Complement 3 glomerulopathy (C3G: a type of kidney disease)

B. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
   1. You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to the body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [type of protein in red blood cells] levels) compared to baseline (before treatment)
   2. You will NOT use Fabhalta concurrently (at the same time) with a C5 complement inhibitor (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor (such as Empaveli [pegcetacoplan]) or Factor D inhibitor (such as Voydeya [danicopan])

C. If you have primary immunoglobulin A nephropathy, renewal also requires:
   1. You meet ONE of the following:
      a. You have had a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)
      b. You have improved or stable kidney function compared to baseline (before starting Fabhalta)

D. If you have complement 3 glomerulopathy, renewal also requires:
   1. You have improved or stable kidney function compared to baseline (before treatment) OR you have a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)
   2. You will NOT use Fabhalta concurrently (at the same time) with another complement inhibitor (such as Empaveli [pegcetacoplan]) for the treatment of complement 3 glomerulopathy (a type of kidney disease)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IPTACOPAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fabhalta.

REFERENCES

Fabhalta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2025.

Created: 12/23
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IRINOTECAN LIPOSOMAL (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IRINOTECAN LIPOSOMAL	ONIVYDE	42715		GPI-10 (2155004020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic pancreatic adenocarcinoma **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - Onivyde will be used in combination with oxaliplatin, fluorouracil and leucovorin as first-line treatment
   - Onivyde will be used in combination with fluorouracil and leucovorin AND the patient has experienced disease progression following gemcitabine-based therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a fill limit of #2 fills per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IRINOTECAN LIPOSOMAL (Onivyde)** requires the following rule(s) be met for approval:
   A. You have metastatic pancreatic adenocarcinoma (a type of cancer of the pancreas that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You meet ONE of the following:
      1. Onivyde will be used in combination with oxaliplatin, fluorouracil and leucovorin as first-line treatment (used for initial treatment)
      2. Onivyde will be used in combination with fluorouracil and leucovorin AND you have experienced disease progression (disease has worsened) following gemcitabine-based therapy (a type of cancer drug)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IRINOTECAN LIPOSOMAL (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Onivyde.

REFERENCES

Onivyde [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; February 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 03/04/24
Created: 11/15
Client Approval: 02/24
P&T Approval: 04/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISATUXIMAB-IRFC (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ISATUXIMAB-IRFC	SARCLISA	46389		GPI-10 (2135403320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Sarclisa is used in combination with Pomalyst (pomalidomide) and dexamethasone
   - The patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g., Ninlaro [ixazomib], Kyprolis [carfilzomib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Sarclisa is used in combination with Kyprolis (carfilzomib) and dexamethasone
   - The patient has received one to three prior lines of therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have newly diagnosed multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Sarclisa is used in combination with Velcade (bortezomib), Revlimid (lenalidomide) and dexamethasone
   - The patient is not eligible for autologous stem cell transplant (ASCT)

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ISATUXIMAB-IRFC (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ISATUXIMAB-IRFC (Sarclisa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Multiple myeloma (type of blood cancer)
   2. Relapsed or refractory multiple myeloma (type of blood cancer that has returned or no longer responds to treatment)

B. If you have multiple myeloma, approval also requires:
   1. You are 18 years of age or older
   2. Sarclisa will be used in combination with Pomalyst (pomalidomide) and dexamethasone
   3. You have received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (such as Ninlaro [ixazomib], Kyprolis [carfilzomib])

C. If you have relapsed or refractory multiple myeloma, approval also requires:
   1. You are 18 years of age or older
   2. Sarclisa will be used in combination with Kyprolis (carfilzomib) and dexamethasone
   3. You have received one to three prior lines of therapy

D. If you have newly diagnosed multiple myeloma, approval also requires:
   1. You are 18 years of age or older
   2. Sarclisa will be used in combination with Velcade (bortezomib), Revlimid (lenalidomide) and dexamethasone
   3. You are not eligible for autologous stem cell transplant (ASCT: a type of treatment that uses your own healthy blood cells)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sarclisa.

REFERENCES

Sarclisa [Prescribing Information]. Bridgewater, NJ: Sanofi-aventis U.S. LLC, September 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/21/24
Created: 05/20
Client Approval: 10/24
P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISAVUCONAZONIUM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ISAVUCONAZONIUM SULFATE	CRESEMBA		38095 54696	GPI-14 (11407030110125, 11407030110115)	

GUIDELINES FOR USE

1. Is this request for continuation of therapy after the patient was started on Cresemba in the hospital?

   If yes, **approve the requested strength for 6 months by GPID or GPI-14 with a quantity limit as follows:**
   - **74.5 mg: #150 per 30 days.**
   - **186 mg: #60 per 30 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of invasive aspergillosis (ICD-10 Group B44) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older and weighs at least 16 kg (35.2 lb)
   - Therapy is prescribed by or in consultation with an infectious disease specialist
   - The patient had a trial of or contraindication to voriconazole

   If yes, **approve the requested strength for 6 months total by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit as follows:**
     - **74.5 mg: #170 per 30 days for 1 fill.**
     - **186 mg: #68 per 30 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit as follows (enter a start date of 3 days before the end date of the first approval):**
     - **74.5 mg: #150 per 30 days.**
     - **186 mg: #60 per 30 days.**

   SUBSEQUENT REQUESTS:
   - **Approve the requested strength for 6 months with a quantity limit as follows:**
     - **74.5 mg: #150 per 30 days.**
     - **186 mg: #60 per 30 days.**

   If no, continue to #3.

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ISAVUCONAZONIUM

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of invasive mucormycosis (ICD-10 B46.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older and weighs at least 16 kg (35.2 lb)
   - Therapy is prescribed by or in consultation with an infectious disease specialist

   If yes, **approve the requested strength for 6 months total by GPID or GPI-14 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit as follows:**
     - **74.5 mg: #170 per 30 days for 1 fill.**
     - **186 mg: #68 per 30 days for 1 fill.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit as follows (enter a start date of 3 days before the end date of the first approval):**
     - **74.5 mg: #150 per 30 days.**
     - **186 mg: #60 per 30 days.**

   SUBSEQUENT REQUESTS:
   - **Approve the requested strength for 6 months with a quantity limit as follows:**
     - **74.5 mg: #150 per 30 days.**
     - **186 mg: #60 per 30 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ISAVUCONAZONIUM (Cresemba)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. This is a request for continuation of therapy after you were started on Cresemba in the hospital
      2. You have invasive aspergillosis (a type of fungal infection)
      3. You have invasive mucormycosis (a type of fungal infection)

   B. If you have invasive aspergillosis, approval also requires:
      1. You are 6 years of age or older and weigh at least 16 kilograms (35.2 pounds)
      2. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
      3. You have tried or have a contraindication to (harmful for you to use) voriconazole

   (Denial text continued on next page)

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ISAVUCONAZONIUM

GUIDELINES FOR USE (CONTINUED)

C. If you have invasive mucormycosis, approval also requires:
1. You are 6 years of age or older and weigh at least 16 kilograms (35.2 pounds)
2. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cresemba.

REFERENCES

Cresemba [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc; December 2023.

Created: 05/21
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ISTRADEFYLLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ISTRADEFYLLINE	NOURIANZ	45994		GPI-10 (7340102500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease (PD) (ICD-10 Group G20) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient is experiencing 'OFF' episodes
- Nourianz will be used concurrently with levodopa/carbidopa (e.g., Sinemet, Sinemet CR)

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **TWO** Parkinson's disease agents from different medication classes as follows?
- Dopamine agonists (e.g., ropinirole, pramipexole, rotigotine)
- Monoamine oxidase-inhibitors (e.g., selegiline, rasagiline)
- Catechol-O-methyl transferase inhibitors (e.g., entacapone, tolcapone)

If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ISTRADEFYLLINE (Nourianz)** requires the following rule(s) be met for approval:
A. You have Parkinson's disease (a type of movement disorder)
B. You are 18 years of age or older
C. You are experiencing 'OFF' episodes (period of symptoms in between doses)
D. You will use Nourianz concurrently (together) with levodopa/carbidopa(such as Sinemet, Sinemet CR [extended-release])
E. You have tried or have a contraindication to (harmful for you to use) TWO Parkinson's disease medications from different medication classes as follows:
   1. Dopamine agonists (such as ropinirole, pramipexole, rotigotine)
   2. Monoamine oxidase-inhibitors (such as selegiline, rasagiline)
   3. Catechol-O-methyl transferase inhibitors (such as entacapone, tolcapone)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ISTRADEFYLLINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nourianz.

REFERENCES

Nourianz [Prescribing Information]. Princeton, NJ: Kyowa Kirin, Inc.; March 2023.

Created: 11/19
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 10/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE - TOLSURA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ITRACONAZOLE	TOLSURA		45848	GPI-14 (11407035000113)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of blastomycosis (pulmonary and extrapulmonary) (ICD-10 Group B40)?

   If yes, continue to #4.
   If no, continue to #2.

2. Does the patient have a diagnosis of histoplasmosis (including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis) (ICD-10 Group B39)?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have a diagnosis of aspergillosis (pulmonary and extrapulmonary) (ICD-10 Group B44) **AND** meet the following criterion?
   - The patient is intolerant or refractory to amphotericin B therapy

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an infectious disease specialist
   - The patient had a trial of a generic itraconazole formulation
   - Tolsura is prescribed due to a subclinical response to other formulations of itraconazole suspected to be due to poor bioavailability

   If yes, **approve for a total of 12 months by GPID or GPI-14 as follows:**
   <u>INITIAL REQUESTS</u>
   - **FIRST APPROVAL: approve for 1 fill with a quantity limit of #126 per 30 days.**
   - **SECOND APPROVAL: approve for 11 months with a quantity limit of #120 per 30 days.**

   <u>SUBSEQUENT REQUESTS</u>
   - **Approve for 12 months with a quantity limit of #120 per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ITRACONAZOLE - TOLSURA

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ITRACONAZOLE - TOLSURA** requires the following rule(s) be met for approval:

A. You have ONE of the following fungal infections:
   1. Blastomycosis (pulmonary and extrapulmonary) (a type of fungal infection affecting in and outside of the lungs)
   2. Histoplasmosis (a type of fungal infection) (including chronic cavitary pulmonary [affecting the lungs] disease and disseminated, nonmeningeal [not affecting spinal cord and brain membranes] histoplasmosis)
   3. Aspergillosis (pulmonary and extrapulmonary) (a type of fungal infection in and outside of the lungs)

B. If you have blastomycosis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
   3. You have tried a generic itraconazole formulation
   4. Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of medication in the body that has an effect)

C. If you have histoplasmosis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
   3. You have tried a generic itraconazole formulation
   4. Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of medication in the body that has an effect)

D. If you have aspergillosis, approval also requires:
   1. You are 18 years of age or older
   2. You are intolerant or refractory (not responsive) to amphotericin B therapy
   3. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
   4. You have tried a generic itraconazole formulation
   5. Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of medication in the body that has an effect)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ITRACONAZOLE - TOLSURA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tolsura.

REFERENCES

Tolsura [Prescribing Information]. Raleigh, NC: Mayne Pharma; October 2024.

Created: 03/19
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IVACAFTOR	KALYDECO	38461		GPI-10 (4530203000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Kalydeco will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient has a responsive mutation in the CFTR gene
   - The patient is NOT homozygous for the F508del mutation in the CFTR gene

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You are 1 month of age or older
   C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
   D. You will NOT use Kalydeco concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   E. You have a responsive mutation in the CFTR gene (abnormal change in a type of gene that can be treated with Kalydeco)
   F. You are NOT homozygous (have two copies of the same gene) for the F508del mutation (abnormal change) in the CFTR gene

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IVACAFTOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Kalydeco will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Kalydeco concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kalydeco.

REFERENCES

Kalydeco [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; August 2023.

Created: 02/12
Effective: 01/28/25 Client Approval: 01/25 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IVOSIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IVOSIDENIB	TIBSOVO	45096		GPI-10 (2153494000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia (AML) (ICD-10 Group C92.0)?

   If yes, continue to #2.
   If no, continue to #5.

2. Is the patient newly diagnosed (e.g., starting or previously started Tibsovo treatment at the time of diagnosis) and meets **ALL** of the following criteria?
   - Tibsovo will be used in combination with azacitidine (Onureg) or as monotherapy
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient is between 18 and 74 years of age with comorbidities that prevent the use of intensive induction chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient's cancer relapsed or is refractory and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IVOSIDENIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of myelodysplastic syndromes (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has relapsed or is refractory
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #6.

6. Does the patient have a diagnosis of cholangiocarcinoma (ICD-10 C22.1, C24.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is locally advanced or metastatic
   - The patient's cancer has been previously treated
   - The patient's cancer has an isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IVOSIDENIB (Tibsovo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)
      2. Myelodysplastic syndromes (MDS: a type of blood cancer)
      3. Cholangiocarcinoma (bile duct cancer)

   (Denial text continued on next page)

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IVOSIDENIB

GUIDELINES FOR USE (CONTINUED)

B. If you have newly diagnosed acute myeloid leukemia (such as you are starting or previously started Tibsovo treatment at the time your condition was identified), approval also requires:
1. Tibsovo will be used in combination with azacitidine (Onureg) or as monotherapy (one drug treatment)
2. Your cancer has a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
3. You meet ONE of the following:
   a. You are 75 years of age or older
   b. You are between 18 and 74 years of age AND you have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of initial therapy to treat cancer)

C. If you have relapsed or refractory acute myeloid leukemia (cancer that has returned or has not responded to treatment), approval also requires:
1. You are 18 years of age or older
2. Your cancer has a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

D. If you have myelodysplastic syndromes, approval also requires:
1. You are 18 years of age or older
2. Your cancer has relapsed or is refractory (cancer that has returned or has not responded to treatment)
3. Your cancer has a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

E. If you have cholangiocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
3. Your cancer has been previously treated
4. Your cancer has an isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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IVOSIDENIB

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tibsovo.

REFERENCES
Tibsovo [Prescribing Information]. Boston, MA: Servier Pharmaceuticals; October 2023.

Created: 11/18
Effective: 08/11/25 Client Approval: 07/25 P&T Approval: 01/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IXABEPILONE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IXABEPILONE	IXEMPRA	35083		GPI-10 (2150001100)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or locally advanced breast cancer?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the requested medication being used in combination with Xeloda (capecitabine)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient tried a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) and a taxane (paclitaxel or docetaxel)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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IXABEPILONE (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IXABEPILONE** requires the following rule(s) be met for approval:

A. You have metastatic (cancer that has spread to other parts of body) or locally advanced breast cancer
B. You meet **ONE** of the following:

1. You had a trial of a chemotherapy (drugs used to treat cancer) regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) **OR**
2. You had a trial of a chemotherapy (drugs used to treat cancer) regimen containing an anthracycline (doxorubicin or epirubicin), and a taxane (paclitaxel or docetaxel) **AND** the requested medication is being used in combination with Xeloda (capecitabine)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ixempra.

REFERENCES

Ixempra [Prescribing Information]. Princeton, NJ. R-Pharm US LLC; January 2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/13
Client Approval: 04/20
P&T Approval: 08/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IXAZOMIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IXAZOMIB CITRATE	NINLARO	42826		GPI-10 (2153604510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - Ninlaro will be used in combination with Revlimid (lenalidomide) and dexamethasone
   - The patient has received at least one prior therapy for the treatment of multiple myeloma (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], Thalomid **[**thalidomide], Revlimid [lenalidomide], Alkeran [melphalan], stem cell transplantation)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **IXAZOMIB (Ninlaro)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (a type of blood cancer)
   B. Ninlaro will be used in combination with Revlimid (lenalidomide) and dexamethasone
   C. You have received at least one prior therapy (such as Velcade [bortezomib], Kyprolis [carfilzomib], Thalomid [thalidomide], Revlimid [lenalidomide], Alkeran [melphalan], stem cell transplantation [a type of procedure])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ninlaro.

REFERENCES

Ninlaro [Prescribing Information]. Cambridge, MA: Takeda Pharmaceutical America, Inc.; July 2024.

Created: 12/15
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 02/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

IXEKIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IXEKIZUMAB	TALTZ SYRINGE, TALTZ AUTOINJECTOR	43193		GPI-10 (9025055400)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Taltz
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, genital area, face, or scalp

   If yes, **approve as follows:**
   - **For patients who are 6 to 17 years of age, approve all formulations and strengths for 6 months by GPID or GPI-14 as follows:**
     - **80 mg/mL: #1 mL per 28 days**
     - **40 mg/0.5 mL: #0.5 mL per 28 days**
     - **20 mg/0.25 mL: #0.25 mL per 28 days**

     (Please also enter proactive PAs for all formulations of the 80 mg/mL strength for 1 month with a quantity limit of #2 mL per 28 days.)
   - **For patients who are 18 years of age or older, approve all formulations of the 80 mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1 mL per 28 days.**

     (Please also enter proactive PAs for all formulations of the 80 mg/mL strength by GPID or GPI-14 as follows:
     - **Approve for 1 month with a quantity limit of #3 mL per 28 days.**
     - **Approve for 2 months with a quantity limit of #2 mL per 28 days. Enter a start date of 1 WEEK BEFORE the END date of the above 1-month approval)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 80 mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1 mL per 28 days.**
   (Please also enter proactive PAs for all formulations of the 80 mg/mL strength for 1 month with a quantity limit of #2 mL per 28 days.)

   If no, continue to #5.

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, **approve all formulations of the 80 mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1 mL per 28 days.**
   (Please also enter proactive PAs for all formulations of the 80 mg/mL strength for 1 month by GPID or GPI-14 with a quantity limit of #2 mL per 28 days.)

   If no, continue to #6.

6. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Cimzia [certolizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Taltz
   - The patient has C-reactive protein (CRP) levels above the upper limit of normal
   - The patient has sacroiliitis on magnetic resonance imaging (MRI)

   If yes, **approve all formulations of the 80mg/mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

B. If you have moderate to severe plaque psoriasis, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Taltz
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp

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IXEKIZUMAB

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)

E. If you have non-radiographic axial spondyloarthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Cimzia [certolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
5. You meet ONE of the following:
   a. You were previously stable on another biologic and are switching to Taltz
   b. You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
   c. You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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IXEKIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve all strengths and formulations for 12 months by GPID or GPI-14 as follows:**
   - **80mg/mL: #1mL per 28 days.**
   - **40mg/0.5mL: #0.5mL per 28 days.**
   - **20mg/0.25mL: #0.25mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve all formulations of the 80mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

   If no, continue to #3.

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve all formulations of the 80mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

   If no, continue to #4.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   - Taltz will NOT be used concurrently with another systemic biologic (e.g., Cimzia [certolizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA

   If yes, **approve all formulations of the 80mg/mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **IXEKIZUMAB (Taltz)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)

B. If you have moderate to severe plaque psoriasis, renewal also requires:
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

C. If you have psoriatic arthritis, renewal also requires:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

D. If you have ankylosing spondylitis, renewal also requires:
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
   2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis

(Renewal denial text continued on next page)

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IXEKIZUMAB

RENEWAL CRITERIA (CONTINUED)

E. If you have non-radiographic axial spondyloarthritis, renewal also requires:

1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) score while on therapy
2. You will NOT use Taltz concurrently (at the same time) with another systemic biologic (such as Cimzia [certolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Taltz.

REFERENCES

Taltz [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; August 2024.

Created: 04/16
Effective: 07/22/26 Client Approval: 07/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LACOSAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LACOSAMIDE	MOTPOLY XR		54119 54121 54122	GPI-14 (72600036007030, 72600036007020, 72600036007025)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Groups G40.1, G40.2) and meet **ALL** of the following criteria?
   - The patient weighs at least 50 kg (110 lbs.)
   - The patient had a trial of or contraindication to THREE generic antiepileptic medications (e.g., carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide, topiramate, lamotrigine)
   - The patient is unable to tolerate lacosamide immediate-release

   If yes, **approve for a total of 12 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve all strengths for 1 month with the following quantity limits:**
     - **100 mg: #4 per day.**
     - **150 mg: #2 per day.**
     - **200 mg: #2 per day.**
   - **SECOND APPROVAL: Approve the requested strength for 11 months with the following quantity limits (please enter a start date of 3 days BEFORE the END date of the first approval):**
     - **100 mg: #1 per day.**
     - **150 mg: #2 per day.**
     - **200 mg: #2 per day.**

   If no, continue to #2.

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LACOSAMIDE

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of primary generalized tonic-clonic seizures (ICD-10 Group G40.3) and meet **ALL** of the following criteria?
   - The patient weighs at least 50 kg (110 lbs)
   - Motpoly XR will be used as adjunctive treatment
   - The patient had a trial of or contraindication to THREE generic antiepileptic medications (e.g., carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide, topiramate, lamotrigine)
   - The patient is unable to tolerate lacosamide immediate-release

   If yes, **approve for a total of 12 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve all strengths for 1 month with the following quantity limits:**
     - **100 mg: #4 per day.**
     - **150 mg: #2 per day.**
     - **200 mg: #2 per day.**
   - **SECOND APPROVAL: Approve the requested strength for 11 months with the following quantity limits (please enter a start date of 3 days BEFORE the END date of the first approval):**
     - **100 mg: #1 per day.**
     - **150 mg: #2 per day.**
     - **200 mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LACOSAMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LACOSAMIDE (Motpoly XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Partial-onset seizures (a type of seizure)
   2. Primary generalized tonic-clonic seizures (a type of seizure)

B. If you have primary-onset seizures, approval also requires:
   1. You weigh at least 50 kilograms (110 pounds)
   2. You have tried or have a contraindication to (harmful for you to use) THREE generic anti-seizure medications (such as carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine)
   3. You are not able to tolerate lacosamide immediate-release

C. If you have primary generalized tonic-clonic seizures, approval also requires:
   1. You weigh at least 50 kilograms (110 pounds)
   2. Motpoly XR will be used as adjunctive (add-on) treatment
   3. You have tried or have a contraindication to (harmful for you to use) THREE generic anti-seizure medications (such as carbamazepine, divalproex sodium, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine)
   4. You are not able to tolerate lacosamide immediate-release

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LACOSAMIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Groups G40.1, G40.2)?

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100 mg: #1 per day.**
   - **150 mg: #2 per day.**
   - **200 mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of primary generalized tonic-clonic seizures (ICD-10 Group G40.3)?

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100 mg: #1 per day.**
   - **150 mg: #2 per day.**
   - **200 mg: #2 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LACOSAMIDE (Motpoly XR)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Partial-onset seizures (a type of seizure)
      2. Primary generalized tonic-clonic seizures (a type of seizure)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Motpoly XR.

REFERENCES

Motpoly XR [Prescribing Information]. Piscataway, NJ: Aucta Pharmaceuticals, Inc.; June 2024.

Created: 11/23
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LACTIC ACID/CITRIC/POTASSIUM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LACTIC ACID/CITRIC/POTASSIUM	PHEXX	46568		GPI-10 (5532990340)	

Please refer to CONTRACEPTIVE ZERO COST SHARE OVERRIDE section below if the request is also for zero copay override.

GUIDELINES FOR USE

1. Is the request for prevention of pregnancy in a female patient with reproductive potential and the patient meets **ALL** of the following criteria?
   - Phexx will NOT be used concurrently with vaginal ring products (e.g., Annovera, Nuvaring)
   - The patient had a trial of or contraindication to TWO preferred contraceptive agents (e.g., intrauterine device [Mirena, Kyleena, Liletta, Skyla, ParaGard], hormonal implant/injection/patch/oral products [Nexplanon, Depo-Provera, Xulane, etc.])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #60 grams per 30 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LACTIC ACID/CITRIC/POTASSIUM (Phexx)** requires the following rule(s) be met for approval:
   A. You are a female patient with reproductive potential using the requested medication for prevention of pregnancy
   B. You will NOT use Phexx concurrently (at the same time) with vaginal ring products (such as Annovera, Nuvaring)
   C. You have tried or have a contraindication to (harmful for you to use) TWO preferred contraceptive medications (such as an intrauterine device [Mirena, Kyleena, Liletta, Skyla, ParaGard], hormonal implant, injection, patch, or oral products [Nexplanon, Depo-Provera, Xulane])

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LACTIC ACID/CITRIC/POTASSIUM

GUIDELINES FOR USE (CONTINUED)

CONTRACEPTIVE ZERO COST SHARE OVERRIDE CRITERIA

1. Is the patient requesting a cost share exception for the requested contraceptive agent **AND** does the plan cover contraceptives at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Do **ANY** of the following criteria apply?
   - The patient's plan has specific procedures, instructions, and/or policies for cost share exception processes or for multi-source brand agent overrides (DAW1 override)
   - The request is for an agent with an excluded route of administration, such that the agent will be covered on the medical benefit

   If yes, guideline does not apply.
   If no, continue to #3.

3. Is the request for a generic agent?

   If yes, **approve for 12 months by HICL or GPI-10 at zero copay.**
   If no, continue to #4.

4. Is the request for **ONE** of the following?
   - A single-source brand (SSB) contraceptive agent that has no preferred generic agents or therapeutically equivalent products available
   - A multi-source brand (MSB) contraceptive agent

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LACTIC ACID/CITRIC/POTASSIUM

GUIDELINES FOR USE - CONTRACEPTIVE ZERO COST SHARE OVERRIDE CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - Two preferred medications are medically inappropriate for the patient (alternatively, one if only one agent is available)
   - The patient has tried or has a documented medical contraindication to two preferred medications (alternatively, a trial of one if only one agent is available)
   - The prescriber provided documentation confirming that the requested drug is considered medically necessary (considerations may include severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service)

   If yes, **approve for 12 months by HICL or GPI-10 at zero copay.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **CONTRACEPTIVE ZERO COST SHARE OVERRIDE** requires that the following rules be met for approval:

   A. The request is for ONE of the following:
      1. A generic contraceptive agent
      2. A single-source brand (SSB) contraceptive agent that has no preferred generic agents or therapeutically equivalent products available
      3. A multi-source brand (MSB) contraceptive agent

   B. If the request is for a single-source brand or multi-source brand contraceptive medication, approval also requires ONE of the following:
      1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
      2. You have tried or have a documented medical contraindication (harmful for) to two preferred medications (or one if only one agent is available)
      3. Your doctor has provided documentation confirming that the requested drug is considered medically necessary for you (considerations may include severity of side effects, differences in durability and reversibility of contraceptive and ability to adhere to the appropriate use)

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LACTIC ACID/CITRIC/POTASSIUM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Phexx.

The Contraceptive Zero Cost Share Override criteria applies to plans where the pharmacy benefit allows for coverage of contraceptives at zero copay. The override criteria allow patient access to all FDA-approved contraceptive methods at zero copay by waiving the applicable cost-sharing for branded or non-preferred branded contraceptives.

The MedImpact standard Zero Copay list currently offers coverage of all methods at zero cost share. The zero cost share list offers a variety of contraceptives. Covered methods (zero cost share) include 1) specified barrier contraceptives (condoms, diaphragms, cervical caps, and nonoxynol-9) 2) generic oral hormonal contraceptives under STC 0248, including generic emergency contraceptives and Ella 3) generic transdermal patch contraceptive (currently marketed by Mylan as Xulane) 4) Nuvaring vaginal ring 5) Intrauterine devices – levonorgestrel IUDs and copper IUDs 6) Depo-Provera injections, 7) Nexplanon implant devices, and 8) Intravaginal contraceptives. The majority of the contraceptives on the EHB Zero cost share list are generic agents, which promotes a cost-effective formulary.
The healthcare.gov website (https://www.healthcare.gov/coverage/birth-control-benefits/) currently recommends: All approved contraceptive methods prescribed by a woman's doctor are covered, including:
Barrier methods (used during intercourse), like diaphragms and sponges
Hormonal methods, like birth control pills and vaginal rings
Implanted devices, like intrauterine devices (IUDs)
Emergency contraception, like Plan B® and Ella®
Sterilization procedures
Patient education and counseling

REFERENCES

Phexx [Prescribing Information]. San Diego, CA: Evofem, Inc., April 2025.
Birth control benefits; https://www.healthcare.gov/coverage/birth-control-benefits/
FAQS About Affordable Care Act Implementation Part 51; https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAMOTRIGINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAMOTRIGINE	SUBVENITE	07378		GPI-10 (7260004000)	BRAND = SUBVENITE

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Group G40.1, Group G40.2)?

   If yes, continue to #2.
   If no, continue to #4.

2. Will Subvenite be used as adjunctive therapy and the patient meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient has a contraindication to or is unable to swallow lamotrigine tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Will Subvenite be used as monotherapy and the patient meets **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - The patient is receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug (AED) but will be switched to Subvenite
   - The patient has a contraindication to or is unable to swallow lamotrigine tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of primary generalized tonic-clonic (PGTC) seizures (ICD-10 Group G40.3) or generalized seizures of Lennox-Gastaut syndrome (ICD-10 Group G40.81), and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Subvenite will be used as adjunctive therapy
   - The patient has a contraindication to or is unable to swallow lamotrigine tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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LAMOTRIGINE

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of bipolar I disorder (ICD-10 Group F31 except Group F31.8) and meet **ALL** of the following criteria?
   - Subvenite will be used for maintenance treatment
   - The patient is receiving treatment with standard therapy (e.g., olanzapine, valproate, lithium) for acute mood episodes (depression, mania, hypomania, mixed episodes)
   - The patient has a contraindication to or is unable to swallow lamotrigine tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LAMOTRIGINE (Subvenite)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Partial-onset seizures (a type of seizure)
      2. Primary generalized tonic-clonic (PGTC) seizures (a type of seizure)
      3. Generalized seizures of Lennox-Gastaut syndrome (a type of seizure disorder in young children)
      4. Bipolar I disorder (a type of mood disorder)

   B. If you have partial-onset seizures, approval also requires ONE of the following:
      1. You will use Subvenite as adjunctive (add-on) therapy and meet ALL of the following:
         a. You are 2 years of age or older
         b. You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets
      2. You will use Subvenite as monotherapy (one medication treatment) and meet ALL of the following:
         a. You are 16 years of age or older
         b. You are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as a single antiepileptic medication (a type of medication used to treat epilepsy or seizures) but you will switch to Subvenite
         c. You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets

   C. If you have primary generalized tonic-clonic seizures or generalized seizures, approval also requires:
      1. You are 2 years of age or older
      2. You will use Subvenite as adjunctive (add-on) therapy
      3. You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets

   (Denial text continued on the next page)

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LAMOTRIGINE

GUIDELINES FOR USE (CONTINUED)

D. If you have bipolar I disorder, approval also requires:
1. You will use Subvenite for maintenance treatment
2. You are receiving treatment with standard therapy (such as olanzapine, valproate, lithium) for acute mood episodes (depression, mania, hypomania, mixed episodes [types of mood disorders])
3. You have a contraindication to (harmful for you to use) or are unable to swallow lamotrigine tablets

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Subvenite.

REFERENCES
Subvenite [Prescribing Information]. Lisle, IL: OWP Pharmaceuticals Inc.; September 2025.

Created: 11/25
Effective: 12/01/25 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LANADELUMAB-FLYO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LANADELUMAB-FLYO	TAKHZYRO	45177		GPI-10 (8584204020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Takhzyro will be used for prophylaxis against HAE attacks
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Takhzyro will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**
If no, continue to #3.

3. Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
- The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
- Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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LANADELUMAB-FLYO

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 2 years of age or older
C. Takhzyro will be used for the prevention of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use Takhzyro concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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LANADELUMAB-FLYO

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?

- The patient has experienced an improvement in HAE attacks (reductions in attack frequency or attack severity) compared to baseline
- Takhzyro will NOT be used concurrently with an alternative prophylactic agent for HAE attacks (e.g., Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.** If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LANADELUMAB-FLYO (Takhzyro)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced an improvement in hereditary angioedema (a type of gene condition with severe body swelling) attacks (reductions in attack frequency or attack severity) compared to baseline (before treatment)
C. You will NOT use Takhzyro concurrently (at the same time) with an alternative preventive medication for hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Cinryze [C1 esterase inhibitor], Haegarda [C1 esterase inhibitor], danazol, Orladeyo [berotralstat], Andembry [garadacimab-gxii], Dawnzera [donidalorsen])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Takhzyro.

REFERENCES

Takhzyro [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; January 2025.

Created: 09/18
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LANREOTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LANREOTIDE ACETATE	SOMATULINE DEPOT, LANREOTIDE ACETATE	10781		GPI-10 (3017005010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had an inadequate response to or cannot be treated with surgery or radiation therapy
   - The patient's serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patient's age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load
   - The patient had a trial of or contraindication to the preferred agent: Sandostatin LAR Depot (octreotide acetate ER)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **60mg/0.2mL: #0.2mL per 28 days.**
   - **90mg/0.3mL: #0.3mL per 28 days.**
   - **120mg/0.5mL: #0.5mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (ICD-10 Group C7A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has unresectable, well or moderately differentiated, locally advanced or metastatic GEP-NETs

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **60mg/0.2mL: #0.2mL per 28 days.**
   - **90mg/0.3mL: #0.3mL per 28 days.**
   - **120mg/0.5mL: #0.5mL per 28 days.**

   If no, continue to #3.

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LANREOTIDE

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of carcinoid syndrome (ICD-10 E34.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **60mg/0.2mL: #0.2mL per 28 days.**
   - **90mg/0.3mL: #0.3mL per 28 days.**
   - **120mg/0.5mL: #0.5mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANREOTIDE (Somatuline Depot)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Acromegaly (a type of hormone disorder)
      2. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs: a rare type of tumor)
      3. Carcinoid syndrome (a set of symptoms caused by a type of tumor that releases substances into the body)

   B. If you have acromegaly, approval also requires:
      1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
      2. You had an inadequate response (did not work) to or cannot be treated with surgery or radiation therapy
      3. Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
      4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Sandostatin LAR Depot (octreotide acetate ER)

   (Initial denial text continued on next page)

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LANREOTIDE

INITIAL CRITERIA (CONTINUED)

C. If you have gastroenteropancreatic neuroendocrine tumors, approval also requires:
1. You are 18 years of age or older
2. You have unresectable (unable to remove by surgery), well or moderately differentiated, locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic (cancer that has spread to other parts of the body) gastroenteropancreatic neuroendocrine tumors (a rare type of tumor)

D. If you have carcinoid syndrome, approval also requires:
1. You are 18 years of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LANREOTIDE

RENEWAL CRITERIA

NOTE: For the diagnoses of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) or carcinoid syndrome, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or has sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **60mg/0.2mL: #0.2mL per 28 days.**
   - **90mg/0.3mL: #0.3mL per 28 days.**
   - **120mg/0.5mL: #0.5mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LANREOTIDE (Somatuline Depot)** requires the following rule(s) be met for renewal:
   A. You have acromegaly (a type of hormone disorder)
   B. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   C. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Somatuline Depot.

REFERENCES

Somatuline Depot [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; July 2024.

Created: 08/22
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAPATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAPATINIB DITOSYLATE	TYKERB, LAPATINIB	34541		GPI-10 (2153302610)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 C79.81, Group C50) and meet **ALL** of the following criteria?
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive
   - The requested medication will be used in combination with Xeloda (capecitabine)
   - The patient has received prior therapy with Herceptin (trastuzumab), an anthracycline (e.g., daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (e.g., paclitaxel, docetaxel)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer (ICD-10 C79.81, Group C50) and meet **ALL** of the following criteria?
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2) positive
   - The patient's tumor is hormone receptor-positive
   - The requested medication will be used in combination with Femara (letrozole)
   - The patient is a postmenopausal woman

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LAPATINIB (Tykerb)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of the body)
   B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   C. If you have advanced breast cancer, approval also requires:
      1. The requested medication will be used in combination with Xeloda (capecitabine)
      2. You have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (such as paclitaxel, docetaxel)

   (Denial text continued on the next page)

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LAPATINIB

GUIDELINES FOR USE (CONTINUED)

D. If you have metastatic breast cancer, approval also requires ONE of the following:

1. The requested medication will be used in combination with Xeloda (capecitabine), AND you have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), and a taxane (such as paclitaxel, docetaxel)
2. The requested medication will be used in combination with Femara (letrozole), your tumor is hormone receptor (HR: a type of protein)-positive, and you are a postmenopausal (after menopause) woman

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tykerb.

REFERENCES

Tykerb [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2022.

Created: 04/10
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 08/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAROTRECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAROTRECTINIB	VITRAKVI	45494		GPI-10 (2153383520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a solid tumor and meet **ALL** of the following criteria?
   - The tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation
   - The tumor is metastatic or surgical resection is likely to result in severe morbidity
   - There are no satisfactory alternative treatments, or the patient has progressed following treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Vitrakvi oral capsules?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Vitrakvi 25mg: #6 capsules per day.**
   - **Vitrakvi 100mg: #2 capsules per day.**

   If no, continue to #3.

3. Is the request for Vitrakvi oral solution and the patient meets **ONE** of the following criteria?
   - The request is for a pediatric patient
   - The patient is unable to take Vitrakvi capsules due to difficulty swallowing or dysphagia
   - The patient has other medical need for the oral solution

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **Vitrakvi 20mg/mL oral solution: #10mL per day.**

   If no, do not approve Vitrakvi oral suspension. **Please enter a proactive PA for Vitrakvi capsules and approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Vitrakvi 25mg: #6 capsules per day.**
   - **Vitrakvi 100mg: #2 capsules per day.**

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LAROTRECTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LAROTRECTINIB (Vitrakvi)** requires the following rule(s) be met for approval:

A. You have a solid tumor (abnormal mass of tissue that usually does not contain cysts or liquid)
B. Your tumor has a neurotrophic receptor tyrosine kinase (*NTRK)* gene fusion without a known acquired resistance mutation (you have a type of enzyme that doesn't have a mutation)
C. Your tumor is metastatic (spreads to other parts of body) or surgical resection (removal) is likely to result in severe morbidity (illness)
D. There are no satisfactory alternative treatments, or your tumor has gotten worse after treatment
E. Requests for Vitrakvi oral solution also require ONE of the following:
    1. You are a pediatric patient (less than 18 years of age)
    2. You are unable to take Vitrakvi capsules due to difficulty swallowing (or dysphagia)
    3. You have other medical need for the oral solution

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vitrakvi.

REFERENCES

Vitrakvi [Prescribing Information]. Stamford, CT: Loxo Oncology, Inc: December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 03/19
Client Approval: 04/20

P&T Approval: 01/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LASMIDITAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LASMIDITAN SUCCINATE	REYVOW	46082		GPI-10 (6740654060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for approval:
   A. The request is for acute (quick onset) treatment of migraines (a type of headache)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LASMIDITAN

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ONE** of the following criteria?
   - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
   - The patient has experienced clinical improvement defined as ability to function normally within 2 hours of dose, headache pain disappears within 2 hours of dose, OR therapy works consistently in majority of migraine attacks

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for renewal:
   A. The request is for acute (quick onset) treatment of migraines (a type of headache)
   B. You meet ONE of the following:
      1. You have experienced an improvement from baseline (before treatment) in a validated acute treatment patient-reported outcome questionnaire (such as Migraine Assessment of Current Therapy [MIGRAINE-ACT: assessment tool used to help guide treatment])
      2. You have experienced clinical improvement as defined by ONE of the following:
         a. Ability to function normally within 2 hours of dose
         b. Headache pain disappears within 2 hours of dose
         c. Treatment works consistently in majority of migraine attacks

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Reyvow.

REFERENCES

Reyvow [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC, September 2022.

Created: 02/20
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LAZERTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LAZERTINIB MESYLATE	LAZCLUZE	49822		GPI-10 (2136004830)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lazcluze will be used in combination with Rybrevant (amivantamab-vmjw) or Rybrevant Faspro (amivantamab-hyaluronidase-lpuj)
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **80mg: #2 per day.**
   - **240mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LAZERTINIB (Lazcluze)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue or lymph nodes or that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Lazcluze will be used in combination with Rybrevant (amivantamab-vmjw) or Rybrevant Faspro (amivantamab-hyaluronidase-lpuj)
   D. Your tumor has epidermal growth factor receptor (EGFR: a type of protein) exon 19 deletions or exon 21 L858R substitution mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LAZERTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lazcluze.

REFERENCES

Lazcluze [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; November 2025.

Created: 08/24
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEBRIKIZUMAB-LBKZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEBRIKIZUMAB-LBKZ	EBGLYSS	49658		GPI-10 (9027304010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - Ebglyss will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and is switching to Ebglyss
   - The patient has atopic dermatitis involving at least 10% of body surface area (BSA)
   - The patient has atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEBRIKIZUMAB-LBKZ

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **ONE** of the following clinical standard of care therapies?
   - Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate)
   - Topical calcineurin inhibitor (e.g., Protopic [tacrolimus], Elidel [pimecrolimus])
   - Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
   - Topical AhR agonist (e.g., Vtama [tapinarof])
   - Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])
   - Phototherapy

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #8mL per 28 days.)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEBRIKIZUMAB-LBKZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **LEBRIKIZUMAB-LBKZ (Ebglyss)** requires the following rule(s) be met for approval:

A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
D. You will NOT use Ebglyss concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)
E. You meet ONE of the following:
    1. You were previously stable on another biologic (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and are switching to Ebglyss
    2. You have atopic dermatitis (a type of skin condition) involving at least 10 percent of body surface area (BSA)
    3. You have atopic dermatitis (a type of skin condition)affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
F. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care therapies:
    1. Topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate)
    2. Topical calcineurin inhibitor (such as Protopic [tacrolimus], Elidel [pimecrolimus])
    3. Topical PDE-4 (phosphodiesterase-4) inhibitor (such as Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
    4. Topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof])
    5. Topical JAK (Janus kinase) inhibitor (such as Opzelura [ruxolitinib])
    6. Phototherapy (a type of light therapy)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEBRIKIZUMAB-LBKZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on Ebglyss
   - Ebglyss will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **LEBRIKIZUMAB-LBKZ (Ebglyss)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
   B. You have shown improvement while on Ebglyss
   C. You will NOT use Ebglyss concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ebglyss.

REFERENCES
Ebglyss [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; June 2026.

Created: 09/24
Effective: 08/21/26 DMC Approval: 06/29/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LECANEMAB-IRMB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LECANEMAB-IRMB	LEQEMBI, LEQEMBI IQLIK	48590		GPI-10 (6205054530)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Alzheimer's disease (ICD-10 Group G30) and meet **ALL** of the following criteria?
   - The patient is 50 years of age or older
   - The patient has mild cognitive impairment or mild dementia
   - Therapy is prescribed by or in consultation with a neurologist or psychiatrist
   - The patient had an amyloid pathology confirmed by positron emission tomography (PET) or detected by CSF-based testing (e.g., Aβ42, total tau [T-tau], phosphorylated tau [P-tau])
   - The patient has a Clinical Dementia Rating (CDR) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE) score of 20-28 at baseline
   - The patient has Alzheimer's Association Workgroup Clinical Stage 3 (cognitive impairment but mostly maintains independence on activities of daily living [ADL]) or Clinical Stage 4 (cognitive impairment with mild functional impairments on instrumental ADLs but independence in basic ADLs) Alzheimer's disease
   - The patient had a baseline brain MRI within one year prior to treatment
   - The patient had genotype testing to determine apolipoprotein E ε4 (ApoE ε4) status prior to initiation of treatment OR the patient/caregiver has been counseled on the risk of treatment and has waived genotype testing
   - The patient is NOT at an increased risk of cerebral bleeding (e.g., evidence of cerebral micro- or macrohemorrhages, superficial siderosis, vasogenic edema, aneurysms or vascular malformations, lacunar infarcts or severe small vessel or white matter disease on screening MRI, uncontrolled bleeding disorder, platelet count less than 50,000 or international normalized ratio greater than 1.5)
   - The requested medication will NOT be used concurrently with any other anti-amyloid agent (e.g., Kisunla [donanemab-azbt]), anticoagulant (e.g., warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (e.g. Plavix [clopidogrel] with aspirin) (monotherapy antiplatelet is acceptable)

   If yes, **approve for 7 months by GPID or GPI-14 for ALL of the following:**
   - **200mg/2mL vial: #1 fill per 14 days.**
   - **500mg/5mL vial: #1 fill per 14 days.**
   - **500mg/2.5mL autoinjector: #10mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LECANEMAB-IRMB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LECANEMAB-IRMB (Leqembi, Leqembi IQLIK)** requires the following rule(s) be met for approval:

A. You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
B. You are 50 years of age or older
C. You have mild cognitive impairment (decreased ability to process, understand, store and remember information) or mild dementia (a type of memory disorder) due to Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
D. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or psychiatrist (a type of mental health doctor)
E. You had an amyloid pathology (abnormal buildup of a type protein) confirmed by positron emission tomography (PET: a type of imaging test) or detected by cerebrospinal fluid (CSF: a type of liquid in the brain and spinal cord)-based testing (such as amyloid-beta 42 [Aβ42], total tau [T-tau], phosphorylated tau [P-tau]) (types of lab tests)
F. You have a Clinical Dementia Rating (CDR: a tool for evaluating memory loss) global score of 0.5 or 1.0, OR a Mini Mental Status Exam (MMSE: a test used to evaluate memory, thinking, and understanding) score of 20 to 28 at baseline (before treatment)
G. You have Alzheimer's Association Workgroup Clinical Stage 3 (cognitive impairment [decreased ability to process, understand, store and remember information] but mostly maintains independence on activities of daily living [ADL: basic everyday tasks]) or Clinical Stage 4 (cognitive impairment with mild functional impairments on instrumental ADLs but independence in basic ADLs) Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)
H. You have had a baseline brain MRI (magnetic resonance imaging: a type of imaging lab) within one year prior to treatment
I. You had genotype testing (a type of lab test) to determine apolipoprotein E ε4 (ApoE ε4: a type of gene) status prior to initiation of treatment OR you/your caregiver have been counseled on the risk of treatment and have waived genotype testing

(Initial denial text continued on next page)

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LECANEMAB-IRMB

INITIAL CRITERIA (CONTINUED)

J. You are NOT at an increased risk of cerebral bleeding (such as evidence of cerebral microhemorrhages [small amount of bleeding in the brain] or macrohemorrhages [large amount of bleeding in the brain], superficial siderosis [a type of small bleeds in the brain], vasogenic edema [a type of brain swelling], aneurysms [weak bulging spot in the blood vessel] or vascular malformations [abnormal blood vessels], lacunar infarcts [brain stroke] or severe small vessel [damaged small blood vessels in the brain] or white matter disease [damaged nerve fibers in the brain] on screening magnetic resonance imaging [MRI: a type of imaging lab], uncontrolled bleeding disorder, platelet [a type of blood cell] count less than 50,000 or international normalized ratio [a blood test to check how long it takes your blood to clot] greater than 1.5)

K. You will NOT use the requested medication concurrently (at the same time) with any other anti-amyloid medication (such as Kisunla [donanemab-azbt]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

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LECANEMAB-IRMB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Alzheimer's disease (ICD-10 Group G30)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is this a first renewal request? (**NOTE:** Renewal request after the Initial approval of 7 months.)

   If yes, continue to #3.
   If no, continue to #6.

3. Does the patient meet **ALL** of the following criteria?
   - The patient has NOT progressed to moderate or severe Alzheimer's disease (dementia with moderate to severe functional impairment) as assessed by Mini Mental Status Exam or Clinical Dementia Rating (CDR-SB) scale and functional status (ADL impairment)
   - The requested medication will NOT be used concurrently with any other anti-amyloid agent (e.g., Kisunla [donanemab-azbt]), anticoagulant (e.g., warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (e.g. Plavix [clopidogrel] with aspirin) (monotherapy antiplatelet is acceptable)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient shown evidence of amyloid-related imaging abnormalities (ARIA) on an MRI scan?

   If yes, continue to #5.
   If no, **approve for 12 months by GPID or GPI-14 for ALL of the following:**
   - **200mg/2mL vial: #1 fill per 14 days.**
   - **500mg/5mLvial : #1 fill per 14 days.**
   - **360mg/1.8mL autoinjector: #7.2mL per 28 days.**
   - **500mg/2.5mL autoinjector: #10mL per 28 days.**

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LECANEMAB-IRMB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have amyloid-related imaging abnormalities with edema/effusion (ARIA-E) or amyloid-related imaging abnormalities with hemorrhage or superficial siderosis (ARIA-H) and meet **ALL** of the following criteria?
   - The patient does NOT have severe symptoms (e.g., multiple ARIA episodes, macrohemorrhages, 10 or more microhemorrhages since the start of treatment, 3 or more superficial siderosis since the start of treatment, severe ARIA, need for anticoagulation)
   - The patient has moderate ARIA (with or without symptoms) and the provider has suspended infusions until a repeat MRI shows ARIA-E has resolved or ARIA-H has stabilized, OR the patient has asymptomatic mild ARIA with continued MRI monitoring until ARIA-E has resolved or ARIA-H has stabilized

   If yes, **approve for 12 months by GPID or GPI-14 for ALL of the following:**
   - **200mg/2mLvial: #1 fill per 14 days.**
   - **500mg/5mL vial: #1 fill per 14 days.**
   - **360mg/1.8mL autoinjector: #7.2mL per 28 days.**
   - **500mg/2.5mL autoinjector: #10mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Is this a subsequent renewal request? (**NOTE**: Renewal request after the first renewal approval of 12 months.)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LECANEMAB-IRMB

RENEWAL CRITERIA (CONTINUED)

7. Does the patient meet **ALL** of the following criteria?
   - The patient has NOT progressed to moderate or severe Alzheimer's disease (dementia with moderate to severe functional impairment) as assessed by Mini Mental Status Exam or Clinical Dementia Rating (CDR-SB) scale and functional status (ADL impairment)
   - The requested medication will NOT be used concurrently with any other anti-amyloid agent (e.g., Kisunla [donanemab-azbt]), anticoagulant (e.g., warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (e.g. Plavix [clopidogrel] with aspirin) (monotherapy antiplatelet is acceptable)

   If yes, **approve for 12 months by GPID or GPI-14 for ALL of the following:**
   - **200mg/2mL vial: #1 fill per 14 days.**
   - **500mg/5mL vial: #1 fill per 14 days.**
   - **360mg/1.8mL autoinjector: #7.2mL per 28 days.**
   - **500mg/2.5mL autoinjector: #10mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LECANEMAB-IRMB (Leqembi, Leqembi IQLIK)** requires the following rule(s) be met for renewal:

   A. You have Alzheimer's disease (a progressive brain disorder that slowly destroys memory and thinking skills)

   B. If the request is for the first renewal request, renewal also requires:
      1. You have NOT progressed to moderate or severe Alzheimer's disease (dementia [a type of memory disorder] with moderate to severe functional impairment) as assessed by Mini Mental Status Exam (a test used to evaluate memory, thinking, and understanding) or Clinical Dementia Rating (CDR-SB: a tool for evaluating memory loss) scale and functional status (activities of daily living [ADL: basic everyday tasks] impairment)
      2. You will NOT use the requested medication concurrently (at the same time) with any other anti-amyloid medication (such as Kisunla [donanemab-azbt]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You do NOT have evidence of amyloid-related imaging abnormalities (ARIA: abnormal differences in the brain) on a magnetic resonance imaging (MRI: a type of imaging) scan
   b. You have a magnetic resonance imaging (MRI: a type of imaging) scan showing amyloid-related imaging abnormalities with edema/effusion (ARIA-E: a type of brain swelling) or amyloid-related imaging abnormalities with hemorrhage or superficial siderosis (ARIA-H: a type of small bleeds in the brain) and meet ALL of the following:
      i. You do NOT have severe symptoms (such as multiple amyloid-related imaging abnormalities [ARIA: abnormal differences in the brain] episodes, macrohemorrhages [large amount of bleeding in the brain], 10 or more microhemorrhages [small amount of bleeding in the brain] since the start of treatment, 3 or more superficial siderosis [a type of small bleeds in the brain] since the start of treatment, severe ARIA, need for anticoagulation [a type of treatment to thin the blood])
      ii. You have moderate amyloid-related imaging abnormalities (ARIA: abnormal differences in the brain) (with or without symptoms) and your doctor has suspended (stopped) infusions until a repeat magnetic resonance imaging (MRI: a type of imaging) scan shows amyloid-related imaging abnormalities with edema/effusion (ARIA-E: a type of brain swelling) has resolved or amyloid-related imaging abnormalities with hemorrhage or superficial siderosis (ARIA-H: a type of small bleeds in the brain) has stabilized, OR you have asymptomatic (showing no symptoms) mild ARIA with continued MRI monitoring until ARIA-E has resolved or ARIA-H has stabilized

C. If the request is a subsequent renewal request, renewal also requires:

1. You have NOT progressed to moderate or severe Alzheimer's disease (dementia [a type of memory disorder] with moderate to severe functional impairment) as assessed by Mini Mental Status Exam (a test used to evaluate memory, thinking, and understanding) or Clinical Dementia Rating (CDR-SB: a tool for evaluating memory loss) scale and functional status (activities of daily living [ADL: basic everyday tasks] impairment)
2. You will NOT use the requested medication concurrently (at the same time) with any other anti-amyloid medication (such as Kisunla [donanemab-azbt]), anticoagulant (such as warfarin, Xarelto [rivaroxaban], Pradaxa [dabigatran], Eliquis [apixaban], Savaysa [edoxaban]), or dual therapy antiplatelet (such as Plavix [clopidogrel] with aspirin) (monotherapy [one medication treatment] antiplatelet is acceptable)

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LECANEMAB-IRMB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leqembi and Leqembi IQLIK.

REFERENCES

Leqembi, Leqembi IQLIK [Prescribing Information]. Nutley, NJ: Eisai Inc.; January 2026.

Created: 01/23
Effective: 08/08/26 DMC Approval: 08/04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEDIPASVIR/SOFOSBUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEDIPASVIR/ SOFOSBUVIR	HARVONI, LEDIPASVIR/ SOFOSBUVIR	41457		GPI-10 (1235990240)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
- The patient is 3 years of age or older
- The patient has genotype 1, 4, 5, or 6 infection

If yes, continue to #2.
If no, continue to #10.

2. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
- The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- Harvoni will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], rosuvastatin, Olysio [simeprevir], Stribild [elvitegravir/cobicistat/emtricitabine/tenofovir], Aptivus [tipranavir]/ritonavir, St. John's wort)
- Harvoni will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Mavyret (pibrentasvir/glecaprevir), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment-naïve and meets **ALL** of the following criteria?
   - The patient has genotype 1 or 4 infection
   - The patient does not have cirrhosis
   - The patient has an HCV RNA level of less than 6 million IU/mL

   If yes, **approve for 8 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **90mg-400mg tablet: #1 per day.**
   - **45mg-200mg tablet: #1 per day.**
   - **33.75mg-150mg pellets: #1 per day.**
   - **45mg-200mg pellets: #2 per day.**

   If no, continue to #5.

5. Is the patient treatment-naïve and meets **ONE** of the following criteria?
   - The patient does not have cirrhosis
   - The patient has compensated cirrhosis (Child-Pugh A)
   - The patient has decompensated cirrhosis (Child-Pugh B or C) AND Harvoni will be used with ribavirin
   - The patient has genotype 1 or 4 infection, is post-liver transplant, does not have cirrhosis, AND Harvoni will be used with ribavirin
   - The patient has genotype 1 or 4 infection, is post-liver transplant, has compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin

   If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **90mg-400mg tablet: #1 per day.**
   - **45mg-200mg tablet: #1 per day.**
   - **33.75mg-150mg pellets: #1 per day.**
   - **45mg-200mg pellets: #2 per day.**

   If no, continue to #6.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have genotype 1 infection and meet **ALL** of the following criteria?
   - The patient is treatment-experienced (previously failed a peginterferon alfa-based regimen)
   - The patient has compensated cirrhosis (Child-Pugh A)

   If yes, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **90mg-400mg tablet: #1 per day.**
   - **45mg-200mg tablet: #1 per day.**
   - **33.75mg-150mg pellets: #1 per day.**
   - **45mg-200mg pellets: #2 per day.**

   If no, continue to #7.

7. Is the patient treatment-experienced (previously failed a peginterferon alfa-based regimen) and meets **ONE** of the following criteria?
   - The patient does not have cirrhosis
   - The patient has genotype 4, 5, or 6 infection AND has compensated cirrhosis (Child-Pugh A)
   - The patient has genotype 1 or 4 infection, is post-liver transplant, does not have cirrhosis, AND Harvoni will be used with ribavirin
   - The patient has genotype 1 or 4 infection, is post-liver transplant, has compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin

   If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **90mg-400mg tablet: #1 per day.**
   - **45mg-200mg tablet: #1 per day.**
   - **33.75mg-150mg pellets: #1 per day.**
   - **45mg-200mg pellets: #2 per day.**

   If no, continue to #8.

8. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   - The patient has decompensated cirrhosis (Child-Pugh B or C)
   - Harvoni will be used with ribavirin

   If yes, **approve for 12 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **90mg-400mg tablet: #1 per day.**
   - **45mg-200mg tablet: #1 per day.**
   - **33.75mg-150mg pellets: #1 per day.**
   - **45mg-200mg pellets: #2 per day.**

   If no, continue to #9.

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have decompensated cirrhosis and meet **ONE** of the following criteria?
   - The patient has a contraindication to ribavirin (ribavirin ineligible)
   - The patient failed prior treatment with a sofosbuvir-based regimen (e.g., Epclusa [sofosbuvir/velpatasvir]) AND Harvoni will be used with ribavirin
   - The patient is post-liver transplant, treatment-experienced, AND Harvoni will be used with ribavirin

   If yes, **approve for 24 weeks by GPID or GPI-14 for the requested strength as follows:**
   - **90mg-400mg tablet: #1 per day.**
   - **45mg-200mg tablet: #1 per day.**
   - **33.75mg-150mg pellets: #1 per day.**
   - **45mg-200mg pellets: #2 per day.**

   If no, continue to #10.

10. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires the following rule(s) be met for approval:
    A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
    B. You are 3 years of age or older
    C. You have genotype 1, 4, 5, or 6 hepatitis C infection (types of hepatitis C virus)
    D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
    E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
    F. You will NOT use Harvoni concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], rosuvastatin, Olysio [simeprevir], Stribild [elvitegravir/cobicistat/emtricitabine/tenofovir], Aptivus [tipranavir]/ritonavir, St. John's wort)

    (Denial text continued on next page)

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

G. You will NOT use Harvoni concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Mavyret (pibrentasvir/glecaprevir), Epclusa (velpatasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

H. If you are treatment-naïve (no prior treatment), approval also requires ONE of the following:

1. You do not have cirrhosis (liver damage and scarring)
2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
3. You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) AND Harvoni will be used with ribavirin, unless you have a contraindication to (harmful for you to use) ribavirin
4. You have genotype 1 or 4 infection, received a liver transplant (replaced your liver), do not have cirrhosis, AND Harvoni will be used with ribavirin
5. You have genotype 1 or 4 infection, received a liver transplant, have compensated cirrhosis (Child-Pugh A), AND Harvoni will be used with ribavirin

I. If you are treatment-experienced (failed prior treatment), approval also requires ONE of the following:

1. You do not have cirrhosis (liver damage and scarring) AND were previously treated with a peginterferon alfa-based regimen
2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) AND were previously treated with a peginterferon alfa-based regimen
3. You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage) AND Harvoni will be used with ribavirin, unless you have a contraindication to (harmful for you to use) ribavirin
4. You have genotype 1 or 4 infection, received a liver transplant (replaced your liver), do not have cirrhosis, had prior treatment with a peginterferon alfa-based regimen, AND Harvoni will be used with ribavirin
5. You have genotype 1 or 4 infection, received a liver transplant, have compensated cirrhosis (Child-Pugh A), had prior treatment with a peginterferon alfa-based regimen, AND Harvoni will be used with ribavirin
6. You have decompensated cirrhosis, failed prior treatment with a sofosbuvir-based regimen (such as Epclusa [sofosbuvir/velpatasvir]) AND Harvoni will be used with ribavirin
7. You have received a liver transplant, have decompensated cirrhosis, AND Harvoni will be used with ribavirin

(Denial text continued on next page)

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LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

J. Harvoni will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Harvoni.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 28, 2023.

Harvoni [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.

Created: 11/14
Effective: 08/04/25 Client Approval: 07/25 P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEFAMULIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEFAMULIN ACETATE	XENLETA		46826	GPI-14 (16240040100320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) (ICD-10 J15.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's CABP infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for continuation of care from an inpatient setting?

   If yes, **approve the 600mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #10 per 5 days for 1 fill.**

   If no, continue to #3.

3. Is therapy prescribed by or in consultation with an Infectious Disease (ID) specialist?

   If yes, **approve the 600mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #10 per 5 days for 1 fill.**

   If no, continue to #4.

4. Has an antimicrobial susceptibility test been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to at least TWO standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Xenleta

   If yes, **approve the 600mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #10 per 5 days for 1 fill.**

   If no, continue to #5.

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LEFAMULIN

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to at least TWO standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

   If yes, **approve the 600mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #10 per 5 days for 1 fill.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEFAMULIN (Xenleta)** requires the following rule(s) be met for approval:
   A. You have community-acquired bacterial pneumonia (CABP: a type of lung infection)
   B. You are 18 years of age or older
   C. Your infection is caused by any of the following susceptible microorganisms (bacteria that the medication can work on): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
   D. You meet ONE of the following:
      1. Your request is for continuation of care from an inpatient setting (a healthcare facility where medical treatment is given overnight or longer)
      2. Therapy is prescribed by or in consultation with an Infectious Disease (ID) specialist (a doctor who specializes in the treatment of infections)
      3. Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
         a. The bacteria at the infection site culture is resistant (medication will not work on that bacteria) to at least TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
         b. Xenleta will work against the bacteria
      4. If an antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) at least TWO standard of care medications for community- acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEFAMULIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenleta.

REFERENCES

Xenleta [Prescribing Information]. Fort Washington, PA: Nabriva Therapeutics US, Inc.; June 2021.

Created: 08/19
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENACAPAVIR - SUNLENCA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENACAPAVIR SODIUM	SUNLENCA	48555		GPI-10 (1210155520)	BRAND = SUNLENCA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) (ICD-10 B20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is treatment-experienced
   - The patient's HIV-1 is multidrug resistant and has failed their current antiretroviral regimen due to resistance, intolerance, or safety considerations

   If yes, **approve all dosage forms by NDC as follows:**
   <u>INITIAL REQUESTS</u>: Approve for a total of 12 months as follows:
   - **FIRST APPROVAL: Approve for 6 months as follows:**
     - **300mg: #5 for 1 fill.**
     - **463.5mg/1.5mL: #3mL for 1 fill.**
   - **SECOND APPROVAL: Approve for 6 months as follows (please enter a start date of 2 weeks BEFORE the END date of the first approval):**
     - **463.5mg/1.5mL: #3mL per 26 weeks.**

   <u>SUBSEQUENT REQUESTS</u>: Approve for 12 months as follows:
   - **463.5mg/1.5mL: #3mL per 26 weeks.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENACAPAVIR - SUNLENCA** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus type 1 (HIV-1: a type of immune system disease caused by a virus)
   B. You are 18 years of age or older
   C. You are treatment-experienced (previously treated)
   D. You have a multidrug resistant (not responding to treatment) HIV-1 infection and have failed your current antiretroviral regimen (HIV treatment) due to resistance, intolerance (side effects), or safety considerations

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LENACAPAVIR - SUNLENCA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sunlenca.

REFERENCES

Sunlenca [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; November 2024.

Created: 01/23
Effective: 08/04/25 Client Approval: 06/25 P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENALIDOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENALIDOMIDE	REVLIMID, LENALIDOMIDE	33412		GPI-10 (9939405000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Will the requested medication be used as induction or consolidation treatment for multiple myeloma (MM)?

   If yes, **approve for 12 months by HICL or GPI-10 for #21 every 28 days.**
   If no, continue to #3.

3. Will the requested medication be used as maintenance treatment for multiple myeloma (MM)?

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of anemia due to a myelodysplastic syndrome (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's myelodysplastic syndrome (MDS) is associated with a deletion 5q abnormality

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of mantle cell lymphoma (MCL) (ICD-10 Group C83.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib)

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days.**
   If no, continue to #6.

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LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of follicular lymphoma (FL) (ICD-10 Group C82) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #7.
   If no, continue to #9.

7. Is the patient's cancer relapsed or refractory and the patient meets **ONE** of the following criteria?
   - The requested medication will be used in combination with Monjuvi (tafasitamab-cxix) and rituximab
   - The requested medication will be used in combination with Epkinly (epcoritamab-bysp) and rituximab

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

8. Has the patient been previously treated **AND** the requested medication will be used in combination with a rituximab product?

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days for 12 fills.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have a diagnosis of marginal zone lymphoma (MZL) (ICD-10 Group C83.0) and meet **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The patient has previously been treated for marginal zone lymphoma (MZL)
   - The requested medication will be used in combination with a rituximab product

   If yes, **approve for 12 months by HICL or GPI-10 for #21 per 28 days for 12 fills.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LENALIDOMIDE (Revlimid)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Multiple myeloma (MM: a type of blood cancer)
   2. Anemia (a type of blood condition) due to a myelodysplastic syndrome (MDS: a type of blood cancer)
   3. Mantle cell lymphoma (MCL: a type of blood cell)
   4. Follicular lymphoma (FL: a type of blood cancer)
   5. Marginal zone lymphoma (MZL: a type of blood cancer)

B. If you have multiple myeloma, approval also requires:
   1. You are 18 years of age or older
   2. The requested medication will be used as induction, consolidation, or maintenance treatment for multiple myeloma

C. If you have anemia due to a myelodysplastic syndrome, approval also requires:
   1. You are 18 years of age or older
   2. Your myelodysplastic syndrome is associated with a deletion 5q abnormality (a type of gene mutation)

D. If you have mantle cell lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have relapsed or progressed (disease has returned or worsened) after two prior therapies, one of which included Velcade (bortezomib)

E. If you have follicular lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have relapsed or refractory follicular lymphoma and meet ONE of the following:
         i. The requested medication will be used in combination with Monjuvi (tafasitamab-cxix) and rituximab
         ii. The requested medication will be used in combination with Epkinly (epcoritamab-bysp) and rituximab
      b. You have been previously treated for follicular lymphoma AND the requested medication will be used in combination with a rituximab product (a type of cancer medication)

(Denial text continued on next page)

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LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

F. If you have marginal zone lymphoma, approval also requires:
1. You are 18 years of age or older
2. You have previously been treated for marginal zone lymphoma
3. The requested medication will be used in combination with a rituximab product (a type of cancer medication)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Revlimid.

REFERENCES
Revlimid [Prescribing Information]. Summit, NJ: Celgene Corporation; March 2023.

Created: 08/12
Effective: 12/15/25 Client Approval: 12/25 P&T Approval: 07/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENIOLISIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENIOLISIB PHOSPHATE	JOENJA	48803		GPI-10 (9939154060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of activated phosphoinositide 3-kinase delta (PI3Kdelta) syndrome (APDS) (ICD-10 D81.82) **AND** meet the following criterion?
   - The patient is 4 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT:

   Our guideline named **LENIOLISIB (Joenja)** requires the following rule(s) be met for approval:
   A. You have activated phosphoinositide 3-kinase delta (PI3Kdelta) syndrome (APDS: a type of mutation that impacts the immune system)
   B. You are 4 years of age or older

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Joenja.

REFERENCES
Joenja [Prescribing Information]. Warren, NJ: Pharming Healthcare Inc.; September 2026.

Created: 04/23
Effective: 09/18/26 Client Approval: 09/26 DMC Approval: 09/22/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LENVATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LENVATINIB MESYLATE	LENVIMA	41756		GPI-10 (2133505420)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of differentiated thyroid cancer (DTC) (ICD-10 C73) and meet **ALL** of the following criteria? (**NOTE**: Differentiated thyroid cancer (DTC) can be classified as papillary (PTC), follicular (FTC), or Hurthle cell)
   - The thyroid cancer is locally recurrent or metastatic
   - The thyroid cancer is progressive
   - The thyroid cancer is refractory to radioactive iodine therapy

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **20 mg daily dose: #2 per day.**
   - **24 mg daily dose: #3 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, continue to #5.

3. Will Lenvima be used in combination with pembrolizumab (Keytruda)?

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **8 mg daily dose: #2 per day.**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **20 mg daily dose: #2 per day.**

   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Will Lenvima be used in combination with everolimus (Afinitor) **AND** the patient meets the following criterion?
   - The patient has tried one anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **8 mg daily dose: #2 per day.**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **18 mg daily dose: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) **AND** meet the following criterion?
   - The patient's cancer is unresectable

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **4 mg every other day: #1 per 2 days.**
   - **4 mg daily dose: #1 per day.**
   - **8 mg daily dose: #2 per day.**
   - **12 mg daily dose: #3 per day.**

   If no, continue to #6.

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of advanced endometrial carcinoma (EC) (ICD-10 C54.1) and meet **ALL** of the following criteria?
   - Lenvima will be used in combination with pembrolizumab (Keytruda)
   - The patient's cancer is mismatch repair proficient (pMMR) OR is not microsatellite instability-high (MSI-H), as determined by an FDA-approved test
   - The patient has experienced disease progression following prior systemic therapy
   - The patient is not a candidate for curative surgery or radiation

   If yes, **approve for 12 months by GPID or GPI-14 based on the following daily dose requirements:**
   - **8 mg daily dose: #2 per day.**
   - **10 mg daily dose: #1 per day.**
   - **14 mg daily dose: #2 per day.**
   - **20 mg daily dose: #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LENVATINIB (Lenvima)** requires the following rule(s) be met for approval:

   A. You have **ONE** of the following:
      1. Differentiated thyroid cancer (DTC: a type of thyroid cancer)
      2. Advanced renal cell carcinoma (RCC: a type of kidney cancer)
      3. Hepatocellular carcinoma (HCC: a type of liver cancer)
      4. Advanced endometrial carcinoma (EC: a type of uterus cancer)

   B. If you have differentiated thyroid cancer, approval also requires:
      1. Your thyroid cancer is locally recurrent (re-appears in the same spot) or metastatic (has spread to other parts of the body)
      2. Your thyroid cancer is progressive (getting worse)
      3. Your thyroid cancer is refractory (has not responded) to radioactive iodine therapy

   (Denial text continued on next page)

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

C. If you have advanced renal cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Lenvima will be used in combination with pembrolizumab (Keytruda)
   b. Lenvima will be used in combination with everolimus (Afinitor) AND you have tried one anti-angiogenic therapy (treatment that stop tumors from growing their own blood vessels, such as Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

D. If you have hepatocellular carcinoma, approval also requires:
1. Your cancer is unresectable (cannot be removed by surgery)

E. If you have advanced endometrial carcinoma, approval also requires:
1. Lenvima will be used in combination with pembrolizumab (Keytruda)
2. Your cancer is mismatch repair proficient (pMMR: your tumor has normal expression of types of protein) OR is not microsatellite instability-high (MSI-H: a type of mutation), as determined by a Food and Drug Administration (FDA)-approved test
3. You have experienced disease progression (worsening) following prior systemic therapy (treatment that targets the entire body)
4. You are not a candidate for curative (to cure) surgery or radiation

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lenvima.

REFERENCES
Lenvima [Prescribing Information]. Nutley, NJ: Eisai, Inc.; January 2025.

Created: 2/15
Effective: 03/01/25 Client Approval: 02/25 P&T Approval: 04/25

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LETERMOVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LETERMOVIR	PREVYMIS	44622		GPI-10 (1220004500)	

GUIDELINES FOR USE

1. Is the request for prophylaxis of cytomegalovirus (CMV) infection and disease in an allogeneic hematopoietic stem cell transplant (HSCT) recipient and the patient meets **ALL** of the following criteria?
   - The patient is 6 months of age or older
   - Therapy is prescribed by or in consultation with a transplant specialist or infectious disease specialist
   - The patient is a CMV-seropositive recipient [R+] of an allogeneic HSCT
   - The patient will start or started Prevymis between Day 0 and Day 28 post-transplant (before or after engraftment)

   If yes, continue to #2.
   If no, continue to #4.

2. Will the patient receive Prevymis beyond 100 days post-transplant?

   If yes, continue to #3.

   If no, **approve for 100 days by GPID or GPI-14 for all strengths as follows:**
   - **240mg tablet: #1 per day.**
   - **480mg tablet: #1 per day.**
   - **240mg/12mL vial: #12mL per day.**
   - **480mg/24mL vial: #24mL per day.**
   - **20mg pellet: #4 per day.**
   - **120mg pellet: #4 per day.**

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LETERMOVIR

GUIDELINES FOR USE (CONTINUED)

3. Is the patient at risk for late CMV infection and disease, **AND** will not receive Prevymis beyond 200 days post-transplant?

   If yes, **approve for 200 days by GPID or GPI-14 for all strengths as follows:**
   - **240mg tablet: #1 per day.**
   - **480mg tablet: #1 per day.**
   - **240mg/12mL vial: #12mL per day.**
   - **480mg/24mL vial: #24mL per day.**
   - **20mg pellet: #4 per day.**
   - **120mg pellet: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a transplant specialist or infectious disease specialist
   - The patient is a kidney transplant recipient at high risk (i.e., donor is CMV seropositive, recipient is CMV seronegative [D+/R-])
   - The patient will start or started Prevymis between Day 0 and Day 7 post-transplant
   - The patient will not receive Prevymis beyond 200 days post-transplant

   If yes, **approve for 200 days by GPID or GPI-14 for all strengths as follows:**
   - **240mg tablet: #1 per day.**
   - **480mg tablet: #1 per day.**
   - **240mg/12mL vial: #12mL per day.**
   - **480mg/24mL vial: #24mL per day.**
   - **120mg pellet: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LETERMOVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LETERMOVIR (Prevymis)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Prophylaxis (prevention) of cytomegalovirus (CMV: a type of virus) infection and disease in an allogeneic hematopoietic stem cell transplant (HSCT: cells transplanted from a matching donor) recipient
   2. Prophylaxis of cytomegalovirus (CMV) disease in a kidney transplant recipient

B. If the request is for prophylaxis of cytomegalovirus infection and disease in an allogeneic hematopoietic stem cell transplant recipient, approval also requires:
   1. You are 6 months of age or older
   2. Therapy is prescribed by or in consultation with a transplant specialist or infectious disease specialist (a doctor who specializes in the treatment of infections)
   3. You are a CMV-seropositive recipient [R+] of an allogeneic HSCT
   4. You will start or have started Prevymis between Day 0 and Day 28 post (after)-transplant (before or after engraftment [a type of transplant])
   5. You meet ONE of the following:
      a. You are NOT at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 100 days post (after)-transplant
      b. You are at risk for late CMV infection and disease, AND you will not receive Prevymis beyond 200 days post (after)-transplant

C. If the request is for prophylaxis of cytomegalovirus disease in a kidney transplant recipient, approval also requires:
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a transplant specialist or infectious disease specialist (a doctor who specializes in the treatment of infections)
   3. You are a kidney transplant recipient at high risk (donor is CMV seropositive, recipient is CMV seronegative [D+/R-])
   4. You will start or have started Prevymis between Day 0 and Day 7 post (after)-transplant
   5. You will not receive Prevymis beyond 200 days post (after)-transplant

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LETERMOVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Prevymis.

REFERENCES

Prevymis [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; January 2025.

Created: 02/18
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE DEPOT (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	LEUPROLIDE DEPOT, LUTRATE DEPOT		84594	GPI-14 (21405010152230)	

GUIDELINES FOR USE

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by GPID or GPI-14 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 vial per 12 weeks.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE DEPOT** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
   B. If you have gender dysphoria, approval also requires:
      1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leuprolide Acetate Depot and Lutrate Depot.

REFERENCES

Leuprolide Acetate Depot [Prescribing Information]. Warren, NJ: Cipla USA, Inc.; July 2022.
Lutrate Dept [Prescribing Information]. New Jersey, USA: Avyxa Pharma, LLC; February 2025.

Created: 11/22
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE		84597	GPI-14 (21405010106407)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 kits per 28 days.**
   If no, continue to #3.

3. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #4.

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LEUPROLIDE

INITIAL CRITERIA (CONTINUED)

4. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
      3. Central precocious puberty (CPP: early sexual development in girls and boys)

   B. If you have gender dysphoria, approval also requires:
      1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

   C. If you are female and have central precocious puberty, approval also requires:
      1. You are 2 years of age or older
      2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
      3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
      4. You are/were younger than 8 years of age when your condition started
      5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   (Initial denial text continued on next page)

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LEUPROLIDE

INITIAL CRITERIA (CONTINUED)

D. If you are male and have central precocious puberty, approval also requires:

1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
4. You are/were younger than 9 years of age when your condition started
5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

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LEUPROLIDE

RENEWAL CRITERIA

NOTE: For the diagnosis of advanced prostate cancer, please refer to the Initial Criteria section.

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has NOT reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Central precocious puberty (CPP: early sexual development in girls and boys)

   B. If you have gender dysphoria, renewal also requires:
      1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

   C. If you have central precocious puberty, renewal also requires:
      1. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
      2. You have NOT reached the actual age which corresponds to your current pubertal age

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LEUPROLIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leuprolide.

REFERENCES

Leuprolide acetate [Prescribing Information]. Princeton, NJ: Sandoz Inc.; June 2021.

Created: 09/18
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE MESYLATE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE MESYLATE	CAMCEVI	47414		GPI-10 (2140501055)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 6 months.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE MESYLATE (Camcevi)** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer (a type of cancer that has spread outside of the prostate gland)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Camcevi.

REFERENCES

Camcevi [Prescribing Information]. Durham, NC: Accord BioPharma Inc.; May 2021.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 08/22
Client Approval: 09/22
P&T Approval: 07/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-ELIGARD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	ELIGARD		17377 18155 19219 24301	GPI-14 (21405010106415, 21405010156432, 21405010206435, 21405010256445)	

GUIDELINES FOR USE

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **7.5mg: #1 per month.**
   - **22.5mg: #1 per 3 months.**
   - **30mg: #1 per 4 months.**
   - **45mg: #1 per 6 months.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE-ELIGARD** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

   B. If you have gender dysphoria, approval also requires:
      1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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LEUPROLIDE-ELIGARD

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eligard.

REFERENCES

Eligard [Prescribing Information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; February 2025.

Created: 09/18
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-FENSOLVI (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	FENSOLVI	21102		GPI-10 (3008005025)	BRAND = FENSOLVI

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per 6 months.**
   If no, continue to #3.

3. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per 6 months.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEUPROLIDE-FENSOLVI (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEUPROLIDE-FENSOLVI** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)

B. If you have gender dysphoria, approval also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. If you are female and have central precocious puberty, approval also requires:
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 8 years of age when your condition started
   5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

D. If you are male and have central precocious puberty, approval also requires:
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 9 years of age when your condition started
   5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

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LEUPROLIDE-FENSOLVI (NSA)

RENEWAL CRITERIA

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has NOT reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per 6 months.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE-FENSOLVI** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Central precocious puberty (CPP: early sexual development in girls and boys)

   B. If you have gender dysphoria, renewal also requires:
      1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

   C. If you have central precocious puberty, renewal also requires:
      1. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
      2. You have NOT reached the actual age which corresponds to your current pubertal age

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LEUPROLIDE-FENSOLVI (NSA)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Fensolvi.

REFERENCES
Fensolvi [Prescribing Information]. Fort Collins, CO: Tolmar Inc.; April 2023.

Created: 03/18
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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LEUPROLIDE-LUPRON DEPOT (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	LUPRON DEPOT	21102		GPI-10 (2140501010, 2140501015, 2140501020, 2140501025)	BRAND = LUPRON DEPOT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer?

   If yes, **approve for 12 months for all strengths as follows:**
   - **Approve by GPID or GPI-14:**
     - **7.5mg: #1 per 4 weeks.**
     - **22.5mg: #1 per 12 weeks.**
     - **30mg: #1 per 16 weeks.**
   - **Approve by NDC or GPI-14:**
     - **45mg: #1 per 24 weeks.**

   If no, continue to #3.

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LEUPROLIDE-LUPRON DEPOT (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe pain from endometriosis and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The patient had a trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   - Lupron Depot will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa, Myfembree, Zoladex)
   - The patient has NOT received more than 12 months of treatment with Lupron Depot per lifetime

   If yes, **approve for 6 months for all strengths as follows:**
   - **3.75mg: Approve by GPID or GPI-14 with a quantity limit of #1 per month.**
   - **11.25mg: Approve by NDC with a quantity limit of #1 per 3 months.**

   If no, continue to #4.

4. Does the patient have a diagnosis of uterine leiomyomata (fibroids) and meet **ALL** of the following criteria?
   - Lupron Depot will be used concomitantly with iron therapy for the preoperative hematologic improvement of anemia caused by fibroids
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)
   - Lupron Depot will NOT be used concurrently with another GnRH-modulating agent (e.g., Oriahnn [elagolix/estradiol/norethindrone], Myfembree [relugolix/estradiol/norethindrone])

   If yes, **approve for 3 months for all strengths as follows:**
   - **3.75mg: Approve by GPID or GPI-14 with a quantity limit of #1 per month.**
   - **11.25mg: Approve by NDC for one fill of #1.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEUPROLIDE-LUPRON DEPOT (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEUPROLIDE-LUPRON DEPOT** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
   3. Moderate to severe pain from endometriosis (condition affecting the uterus)
   4. Uterine leiomyomata (fibroids: noncancerous growths in the uterus)

B. If you have gender dysphoria, approval also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. If you have moderate to severe pain from endometriosis, approval also requires:
   1. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   2. You had a trial of or contraindication (harmful for) to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   3. Lupron Depot will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa, Myfembree, Zoladex)
   4. You have NOT received more than 12 months of treatment with Lupron Depot per lifetime

D. If you have uterine leiomyomata (fibroids), approval also requires:
   1. Lupron Depot will be used with iron therapy for the preoperative (before surgery) hematologic (blood) improvement of anemia (a type of blood condition) caused by fibroids
   2. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   3. You will NOT use Lupron Depot concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Oriahnn [elagolix/estradiol/norethindrone], Myfembree [relugolix/estradiol/norethindrone])

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LEUPROLIDE-LUPRON DEPOT (NSA)

RENEWAL CRITERIA

NOTE: For the diagnoses of advanced prostate cancer or uterine leiomyomata (fibroids), please refer to the Initial Criteria section.

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain from endometriosis and meet **ALL** of the following criteria?
   - The patient has improvement of pain related to endometriosis while on therapy
   - The patient is receiving concomitant add-back therapy (i.e., combination estrogen-progestin or progestin-only contraceptive preparation)
   - Lupron Depot will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa, Myfembree, Zoladex)
   - The patient has NOT received more than 12 months of treatment with Lupron Depot per lifetime

   If yes, **approve for 6 months for all strengths as follows:**
   - **3.75 mg: Approve by GPID or GPI-14 with a quantity limit of #1 per month.**
   - **11.25 mg: Approve by NDC with a quantity limit of #1 per 3 months.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LEUPROLIDE-LUPRON DEPOT (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEUPROLIDE-LUPRON DEPOT** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Moderate to severe pain from endometriosis (condition affecting the uterus)

B. If you have gender dysphoria, renewal also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. If you have moderate to severe pain from endometriosis, renewal also requires:
   1. You experienced improvement of pain related to endometriosis while on therapy
   2. You are receiving add-back therapy (combination estrogen-progestin or progestin-only contraceptive preparation) at the same time
   3. Lupron Depot will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa, Myfembree, Zoladex)
   4. You have NOT received a total of 12 months of treatment with Lupron Depot per lifetime

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lupron Depot.

REFERENCES

Lupron Depot [Prescribing Information]. North Chicago, IL: AbbVie Inc.; September 2025.

Created: 03/18
Effective: 08/07/26 Client Approval: 08/26 DMC Approval: 08/04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-LUPRON DEPOT-PED (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	LUPRON DEPOT–PED	21102		GPI-10 (3008005010, 3008005015, 3008005025)	BRAND = LUPRON DEPOT-PED

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months for the requested strength as follows:**
   - **Lupron Depot-Ped 1-month kit:**
     - **7.5mg: Approve by GPID or GPI-14 with a quantity limit of #1 per month.**
     - **11.25mg: Approve by NDC with a quantity limit of #1 per month.**
     - **15mg: Approve by GPID or GPI-14 with a quantity limit of #1 per month.**
   - **Lupron Depot-Ped 3-month kit:**
     - **11.25mg: Approve by GPID or GPI-14 with a quantity limit of #1 per 3 months.**
     - **30mg: Approve by GPID or GPI-14 with a quantity limit of #1 per 3 months.**
   - **Lupron Depot-Ped 6-month kit:**
     - **45mg: Approve by GPID or GPI-14 with a quantity limit of #1 per 6 months.**

   If no, continue to #3.

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LEUPROLIDE-LUPRON DEPOT-PED (NSA)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months for the requested strength as follows:**
   - **Lupron Depot-Ped 1-month kit:**
     - **7.5mg: Approve by GPID or GPI-14 with a quantity limit of #1 per month.**
     - **11.25mg: Approve by NDC with a quantity limit of #1 per month.**
     - **15mg: Approve by GPID or GPI-14 with a quantity limit of #1 per month.**
   - **Lupron Depot-Ped 3-month kit:**
     - **11.25mg: Approve by GPID or GPI-14 with a quantity limit of #1 per 3 months.**
     - **30mg: Approve by GPID or GPI-14 with a quantity limit of #1 per 3 months.**
   - **Lupron Depot-Ped 6-month kit:**
     - **45mg: Approve by GPID or GPI-14 with a quantity limit of #1 per 6 months.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEUPROLIDE-LUPRON DEPOT-PED (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEUPROLIDE-LUPRON DEPOT-PED** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)

B. If you have gender dysphoria, approval also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. If you are female and have central precocious puberty, approval also requires:
   1. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   2. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   3. You are/were younger than 8 years of age when your condition started
   4. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

D. If you are male and have central precocious puberty, approval also requires:
   1. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   2. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   3. You are/were younger than 9 years of age when your condition started
   4. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

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LEUPROLIDE-LUPRON DEPOT-PED (NSA)

RENEWAL CRITERIA

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has NOT reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months for the requested strength as follows:**
   - **Lupron Depot-Ped 1-month kit:**
     - **7.5mg: Approve by GPID or GPI-14 with a quantity limit of #1 per month.**
     - **11.25mg: Approve by NDC with a quantity limit of #1 per month.**
     - **15mg: Approve by GPID or GPI-14 with a quantity limit of #1 per month.**
   - **Lupron Depot-Ped 3-month kit:**
     - **11.25mg: Approve by GPID or GPI-14 with a quantity limit of #1 per 3 months.**
     - **30mg: Approve by GPID or GPI-14 with a quantity limit of #1 per 3 months.**
   - **Lupron Depot-Ped 6-month kit:**
     - **45mg: Approve by GPID or GPI-14 with a quantity limit of #1 per 6 months.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LEUPROLIDE-LUPRON DEPOT-PED (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEUPROLIDE-LUPRON DEPOT-PED** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)

B. If you have gender dysphoria, renewal also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

C. If you have central precocious puberty, renewal also requires:
   1. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   2. You have NOT reached the actual age which corresponds to your current pubertal age

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lupron Depot-Ped.

REFERENCES

Lupron Depot-Ped [Prescribing Information]. North Chicago, IL: AbbVie Inc.; April 2023.

Created: 03/18
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE-NORETHINDRONE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE/ NORETHINDRONE ACET	LUPANETA PACK	39945		GPI-10 (3008990250)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain from endometriosis and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) OR histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years
   - The patient had a trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   - Lupaneta will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa, Myfembree, Zoladex)
   - The patient has NOT received more than 12 months of treatment with Lupaneta per lifetime

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **3.75 mg-5 mg: #1 per month.**
   - **11.25 mg-5 mg: #1 per 3 months.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LEUPROLIDE- NORETHINDRONE (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEUPROLIDE- NORETHINDRONE (Lupaneta)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Moderate to severe pain from endometriosis (condition affecting the uterus)

B. If you have moderate to severe pain from endometriosis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
   3. Your diagnosis is confirmed by surgical or direct visualization (such as pelvic ultrasound [type of imaging]) or histopathological (tissue) confirmation (such as laparoscopy [type of surgery] or laparotomy [type of surgery]) in the last 10 years
   4. You had a trial of or contraindication (harmful for) to a nonsteroidal anti-inflammatory drug (NSAID: such as ibuprofen, meloxicam, naproxen) AND a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   5. Lupaneta will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa, Myfembree, Zoladex)
   6. You have NOT received more than 12 months of treatment with Lupaneta per lifetime

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEUPROLIDE- NORETHINDRONE (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For gender dysphoria, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe pain from endometriosis and meet **ALL** of the following criteria?
   - The patient has improvement of pain related to endometriosis while on therapy
   - The patient is receiving concomitant add-back therapy (i.e., combination estrogen-progestin or progestin-only contraceptive preparation)
   - The patient has NOT received more than 12 months of treatment with Zoladex per lifetime
   - Lupaneta will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa, Myfembree, Zoladex)

   If yes, **approve for 6 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **3.75 mg-5 mg: #1 per month.**
   - **11.25 mg-5 mg: #1 per 3 months.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEUPROLIDE- NORETHINDRONE (Lupaneta)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe pain from endometriosis (condition affecting the uterus)
   B. You experienced improvement of pain related to endometriosis while on therapy
   C. You are receiving add-back therapy (combination estrogen-progestin or progestin-only contraceptive preparation) at the same time
   D. You have NOT received a total of 12 months of treatment with Lupaneta per lifetime
   E. Lupaneta will NOT be used at the same time with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa, Myfembree, Zoladex)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEUPROLIDE- NORETHINDRONE (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lupaneta.

REFERENCES

Lupaneta [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; October 2013.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 03/18
Client Approval: 01/23
P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVACETYLLEUCINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVACETYLLEUCINE	AQNEURSA	49883		GPI-10 (6200002300)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?

- Therapy is prescribed by or in consultation with a neurologist or geneticist

If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #4 per day.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEVACETYLLEUCINE (Aqneursa)** requires the following rule(s) be met for approval:

A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or geneticist (a doctor who treats gene disorders)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVACETYLLEUCINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?

- The patient has experienced disease improvement or a reduction in disease progression

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LEVACETYLLEUCINE (Aqneursa)** requires the following rule(s) be met for renewal:
A. You have Niemann-Pick disease type C (NPC: a type of genetic condition)
B. You have shown disease improvement or a reduction in disease progression

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aqneursa.

REFERENCES

Aqneursa [Prescribing Information]. Austin, TX: IntraBio Inc.; September 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 10/24
Client Approval: 10/24
P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVAMLODIPINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVAMLODIPINE MALEATE	CONJUPRI, LEVAMLODIPINE MALEATE	46284		GPI-10 (3400006728)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient had a trial of or contraindication to TWO preferred generic dihydropyridine calcium channel blockers (e.g., amlodipine, felodipine, nicardipine)
   - The patient had a trial of or contraindication to TWO other preferred antihypertensive agents in another class (e.g., hydrochlorothiazide, lisinopril, losartan)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVAMLODIPINE (Conjupri)** requires the following rule(s) be met for approval:
   A. You have hypertension (high blood pressure)
   B. You are 6 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) TWO preferred generic dihydropyridine calcium channel blockers (such as amlodipine, felodipine, nicardipine)
   D. You have tried or have a contraindication to (harmful for you to use) TWO other preferred antihypertensive medications in another class (such as hydrochlorothiazide, lisinopril, losartan)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Conjupri.

REFERENCES

Conjupri [Prescribing Information]. CSPC Ouyi Pharmaceutical Co., Ltd.; December 2024.

Created: 10/20
Effective: 03/25/26 Client Approval: 03/26 P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVODOPA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVODOPA	INBRIJA	01897		GPI-10 (7320004000)	ROUTE = INHALATION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
   - Inbrija is being used for intermittent treatment of OFF episodes associated with Parkinson's disease
   - The patient is currently being treated with carbidopa/levodopa
   - Therapy is prescribed by or given in consultation with a neurologist
   - The patient is **NOT** currently taking more than 1600mg of levodopa per day
   - The physician has optimized drug therapy as evidenced by **BOTH** of the following:
     - Change in levodopa/carbidopa dosing strategy or formulation
     - Trial of or contraindication to at least **TWO** Parkinson's disease agents from **TWO** different classes of the following: dopamine agonist (e.g., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (e.g., selegiline, rasagiline), catechol-o-methyl transferase (COMT) inhibitors (e.g., entacapone, tolcapone), adenosine receptor antagonist A2A (e.g., istradefylline)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #10 capsules per day.**
   APPROVAL TEXT: Renewal requires that the patient has experienced improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. Inbrija is being used for intermittent treatment of OFF episodes (times when you have symptoms return due to medication wearing off) associated with Parkinson's disease
   C. You are currently being treated with carbidopa/levodopa
   D. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor)
   (Initial denial text continued on next page)

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LEVODOPA

INITIAL CRITERIA (CONTINUED)

E. You are **NOT** currently taking more than 1600mg of levodopa per day
F. Your doctor has optimized drug therapy as evidenced by **BOTH** of the following:
   1. Change in levodopa/carbidopa dosing strategy or formulation
   2. Trial of or contraindication to (medical reason why you cannot use) at least **TWO** Parkinson's agents from **TWO** different classes of the following: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone), adenosine receptor antagonist A_{2A} (such as istradefylline)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Parkinson's disease **AND** meet the following criterion?
   - The patient had improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10 capsules per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for renewal approval:
   A. You have Parkinson's disease (a nerve system disorder that affects movement)
   B. You had improvement with motor fluctuations during OFF episodes (times when you have symptoms return due to medication wearing off) with the use of Inbrija. Improvements can be in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVODOPA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inbrija.

REFERENCES

Inbrija [Prescribing Information]. Ardsley, NY: Acorda Therapeutics, Inc., September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/19
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P&T Approval: 10/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOKETOCONAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOKETOCONAZOLE	RECORLEV	47743		GPI-10 (3002204000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's syndrome (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is not a candidate for surgery or surgery has not been curative
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has tried or has a contraindication to oral ketoconazole

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for approval:
   A. You have Cushing's syndrome (a type of hormone disorder)
   B. You are 18 years of age or older
   C. You are not a candidate for surgery or surgery has not been curative (to cure)
   D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   E. You have tried or have a contraindication to (harmful for you to use) oral ketoconazole

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOKETOCONAZOLE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's syndrome (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of Cushing's syndrome (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Recorlev

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOKETOCONAZOLE (Recorlev)** requires the following rule(s) be met for renewal:
   A. You have Cushing's syndrome (a type of hormone disorder)
   B. You continue to have improvement of Cushing's syndrome (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
   C. You continue to tolerate treatment with Recorlev

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Recorlev.

REFERENCES

Recorlev [Prescribing Information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; June 2023.

Created: 01/22
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE-ERMEZA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOTHYROXINE SODIUM	ERMEZA		52325	GPI-14 (28100010102024)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism (ICD-10 E89.0, Group E03 except for ICD-10 E03.5) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #14mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - Ermeza will be used as an adjunct to surgery and radioiodine therapy
   - The patient has a contraindication to or is unable to swallow generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #14mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOTHYROXINE-ERMEZA** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
      2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

   B. If you have congenital or acquired hypothyroidism, approval also requires:
      1. You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

   C. If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:
      1. Ermeza will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
      2. You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVOTHYROXINE-ERMEZA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ermeza.

REFERENCES

Ermeza [Prescribing Information]. Morgantown, WV: Mylan Specialty L.P.; April 2022.

Created: 02/23
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE-THYQUIDITY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOTHYROXINE SODIUM	THYQUIDITY		97287	GPI-14 (28100010102023)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism (ICD-10 E89.0, Group E03 except for ICD-10 E03.5) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - Thyquidity will be used as an adjunct to surgery and radioiodine therapy
   - The patient has a contraindication to or is unable to swallow generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOTHYROXINE-THYQUIDITY** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
      2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

   B. If you have congenital or acquired hypothyroidism, approval also requires:
      1. You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

   C. If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:
      1. Thyquidity will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
      2. You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

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LEVOTHYROXINE-THYQUIDITY

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Thyquidity.

REFERENCES

Thyquidity [Prescribing Information]. Largo, FL: VistaPharm, Inc.; November 2020.

Created: 05/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LEVOTHYROXINE-TIROSINT-SOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEVOTHYROXINE SODIUM	TIROSINT-SOL	02849		GPI-10 (2810001010)	BRAND = TIROSINT-SOL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of congenital or acquired hypothyroidism (ICD-10 E89.0, Group E03 except for ICD-10 E03.5) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of thyrotropin-dependent well-differentiated thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - Tirosint-Sol will be used as an adjunct to surgery and radioiodine therapy
   - The patient has a contraindication to or is unable to swallow generic levothyroxine tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LEVOTHYROXINE-TIROSINT-SOL** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Congenital (present from birth) or acquired hypothyroidism (low thyroid function)
      2. Thyrotropin (a type of thyroid hormone)-dependent well-differentiated thyroid cancer

   B. If you have congenital or acquired hypothyroidism, approval also requires:
      1. You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

   C. If you have thyrotropin-dependent well-differentiated thyroid cancer, approval also requires:
      1. Tirosint-Sol will be used as an adjunct (add-on) to surgery and radioiodine therapy (a type of radiation therapy)
      2. You have a contraindication to (harmful for you to use) or are unable to swallow generic levothyroxine tablets

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LEVOTHYROXINE-TIROSINT-SOL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tirosint-Sol.

REFERENCES

Tirosint-Sol [Prescribing Information]. Pambio-Noranco, Switzerland: IBSA Institut Biochimique SA; November 2023.

Created: 07/21
Effective: 04/01/26 Client Approval: 02/26 P&T Approval:01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

L-GLUTAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GLUTAMINE (L-GLUTAMINE)	ENDARI, GLUTAMINE (L-GLUTAMINE)		13365	GPI-10 (8280102000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sickle cell disease (SCD) (ICD-10 Group D57) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a hematologist
- The patient had a trial of or contraindication to the clinical standard of care agent: hydroxyurea

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient between 5 to 17 years of age?

If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #6 packets per day.**

If no, continue to #3.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
- The patient had at least 2 sickle cell crises in the past year (a sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism, or splenic sequestration)
- The patient is having sickle-cell associated symptoms (e.g., pain or anemia) which are interfering with activities of daily living
- The patient has a history of or has recurrent acute chest syndrome (ACS)

If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #6 packets per day.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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L-GLUTAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) be met for approval:

A. You have sickle cell disease (a type of blood disorder)
B. You are 5 years of age or older
C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
D. The patient have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: hydroxyurea
E. If you are 18 years of age or older, approval also requires ONE of the following:
   1. You had at least 2 sickle cell crises in the past year (a sickle cell crisis is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered [injected into the vein] narcotic [a class of medications used to treat pain] or parenterally administered ketorolac, the occurrence of chest syndrome, priapism [prolonged erection of penis], or splenic sequestration [sickle-shaped blood cells trapped in spleen])
   2. You are having sickle-cell associated symptoms (such as pain or anemia [a type of blood condition]) which are interfering with activities of daily living
   3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

L-GLUTAMINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sickle cell disease (ICD-10 Group D57) **AND** meet the following criterion?
   - The patient has maintained or experienced a reduction in acute complications of sickle cell disease (SCD) (e.g., number of sickle cell crises, hospitalizations, acute chest syndrome [ACS])

   If yes, **approve for lifetime by GPID or GPI-10 with a quantity limit of #6 packets per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) be met for renewal:
   A. You have sickle cell disease (a type of blood disorder)
   B. You have maintained or experienced a reduction in acute (short-term) complications of sickle cell disease (such as the number of sickle cell crises, hospitalizations, acute chest syndrome [ACS: chest pain, cough, fever, low oxygen level])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Endari

REFERENCES

Endari [Prescribing Information]. Torrance, CA: Emmaus Medical, Inc; June 2025.

Created: 09/17
Effective: 03/25/26 Client Approval: 03/26 P&T Approval: 01/20

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LIFILEUCEL (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIFILEUCEL	AMTAGVI	49406		GPI-10 (2165104700)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received previous treatment with a PD-1 blocking antibody (e.g., Opdivo [nivolumab], Keytruda [pembrolizumab])
   - The patient has not received a previous dose of Amtagvi per lifetime

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a BRAF V600 mutation positive melanoma?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10 for #1 fill per lifetime.**

3. Has the patient received previous treatment with a BRAF inhibitor (e.g., Tafinlar [dabrafenib], Zelboraf [vemurafenib], Braftovi [encorafenib])?

   If yes, **approve for 12 months by HICL or GPI-10 for #1 fill per lifetime.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LIFILEUCEL (Amtagvi)** requires the following rule(s) be met for approval:
   A. You have unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed by surgery or has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You had previous treatment with a PD-1 blocking antibody (such as Opdivo [nivolumab], Keytruda [pembrolizumab])
   D. You have not had a previous dose of Amtagvi in your lifetime
   E. If you have a BRAF V600 mutation positive melanoma, approval also requires you had previous treatment with a BRAF inhibitor (such as Tafinlar [dabrafenib], Zelboraf [vemurafenib], Braftovi [encorafenib])

   (Denial text continued on the next page)

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LIFILEUCEL (NSA)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Amtagvi.

REFERENCES

Amtagvi [Prescribing Information]. Philadelphia, PA: Iovance Biotherapeutics Manufacturing LLC; February 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 03/04/24
Created: 02/24
Client Approval: 02/24
P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LINVOSELTAMAB-GCPT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LINVOSELTAMAB-GCPT	LYNOZYFIC	50677		GPI-10 (2135204500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least FOUR prior lines of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib]), an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody [e.g., Darzalex [daratumumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LINVOSELTAMAB-GCPT (Lynozyfic)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have received at least FOUR prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody [such as Darzalex [daratumumab])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lynozyfic.

REFERENCES

Lynozyfic [Prescribing Information]. Cambridge, MA: Takeda Pharmaceuticals; July 2025.

Created: 07/25
Effective: 08/04/25 Client Approval: 07/25 P&T Approval: 10/25

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LIRAGLUTIDE - SAXENDA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIRAGLUTIDE	SAXENDA, LIRAGLUTIDE		37637	GPI-10 (6125205000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for weight loss OR weight management (ICD-10 Group E66) and the patient meets **ALL** of the following criteria?
   - There is physician attestation of active enrollment in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
   - Saxenda will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non- alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)

   If yes, **approve for 29 weeks by GPID or GPI-10.**
   If no, continue to #4.

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LIRAGLUTIDE - SAXENDA

INITIAL CRITERIA (CONTINUED)

4. Is the patient 12 to 17 years of age and meets **ALL** of the following criteria?
   - The patient's body weight is greater than 60 kg (132 lbs)
   - The patient's initial body mass index (BMI) corresponds to 30 kg/m(2) or greater to that for adults (see table below)

BMI Cut-offs for Obesity in Patients 12 to 17 years that corresponds to 30 kg/m^2 in Adults

Age	Body Mass Index	
	Males	Females
12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11
15.5	28.60	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

If yes, **approve for 29 weeks by GPID or GPI-10.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LIRAGLUTIDE - SAXENDA** requires the following rule(s) be met for approval:

A. The request is for weight loss or weight management
B. You are 12 years of age or older
C. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
D. You will NOT use Saxenda concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

(Initial denial text continued on next page)

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LIRAGLUTIDE - SAXENDA

INITIAL CRITERIA (CONTINUED)

E. If you are 18 years of age or older, approval also requires ONE of the following before starting weight loss therapy:

1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
2. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
3. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non- alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
4. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

F. If you are 12 to 17 years of age, approval also requires:

1. You have a body weight greater than 60 kilograms (132 pounds)
2. You have an initial body mass index (BMI: a tool for evaluating body fat) corresponding to 30 kg/m(2) for adults

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LIRAGLUTIDE - SAXENDA

RENEWAL CRITERIA

1. Is the request for weight loss OR weight management (ICD-10 Group E66) **AND** the patient meets the following criterion?
   - Saxenda will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 12 to 17 years of age **AND** meets the following criterion?
   - The patient has achieved or maintained at least a 1% weight loss of baseline BMI after at least 12 weeks of treatment on the maximally tolerated dose

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, continue to #3.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non- alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient achieved or maintained at least a 5% weight loss of baseline body weight after 16 weeks of treatment?

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LIRAGLUTIDE - SAXENDA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LIRAGLUTIDE - SAXENDA** requires the following rule(s) be met for renewal:

A. The request is for weight loss or weight management
B. You are 12 years of age or older
C. You will NOT use Saxenda concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
D. If you are 12 to 17 years of age, approval also requires:
    1. You have achieved or maintained at least a 1% weight loss of baseline body mass index (BMI: a tool for evaluating body fat) after at least 12 weeks of treatment on your maximally tolerated dose
E. If you are 18 years of age or older, approval also requires:
    1. You meet ONE of the following before starting weight loss therapy:
        a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
        b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
        c. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
        d. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
    2. You have achieved or maintained at least a 5% weight loss of baseline body weight after 16 weeks of treatment

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LIRAGLUTIDE - SAXENDA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Saxenda.

REFERENCES

Saxenda [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc.; February 2026.

Created: 05/24
Effective: 04/10/26 Client Approval: 04/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LISDEXAMFETAMINE SOLUTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LISDEXAMFETAMINE DIMESYLATE	ARYNTA	34486		GPI-10 (6110002510)	BRAND = ARYNTA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of attention deficit hyperactivity disorder (ADHD) (ICD-10 Group F90) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow lisdexamfetamine capsules or chewable tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe binge eating disorder (ICD-10 F50.81) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow lisdexamfetamine capsules or chewable tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LISDEXAMFETAMINE SOLUTION (Arynta)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Attention deficit hyperactivity disorder (ADHD: a type of mental health disorder)
      2. Moderate to severe binge eating disorder (a type of eating disorder)
   B. You have a contraindication to (harmful for you to use) or are unable to swallow lisdexamfetamine capsules or chewable tablets

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Arynta.

REFERENCES
Arynta [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; June 2025.

Created: 03/26
Effective: 03/28/26 Client Approval: 03/26 P&T Approval: 04/26

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LISINOPRIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LISINOPRIL	QBRELIS	00132		GPI-10 (3610003000)	BRAND = QBRELIS

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow lisinopril tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of heart failure (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - Qbrelis will be used as adjunct therapy
   - The patient has a contraindication to or is unable to swallow lisinopril tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of acute myocardial infarction (ICD-10 Group I21) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow lisinopril tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LISINOPRIL

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LISINOPRIL (Qbrelis)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hypertension (high blood pressure)
   2. Heart failure (a type of heart condition)
   3. Acute myocardial infarction (heart attack)

B. If you have hypertension, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow lisinopril tablets

C. If you have heart failure, approval also requires:
   1. Qbrelis will be used as adjunct (add-on) therapy
   2. You have a contraindication to (harmful for you to use) or are unable to swallow lisinopril tablets

D. If you have acute myocardial infarction, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow lisinopril tablets

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qbrelis.

REFERENCES

Qbrelis [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; April 2023.

Created: 07/25
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 07/25

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LIXISENATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LIXISENATIDE	ADLYXIN	40782		GPI-10 (2717005600)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of type 2 diabetes (ICD-10 Groups E08, E09, E11, E13) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist, cardiologist, nephrologist, family practice, internal medicine, or another healthcare provider who is specialized in diabetic management
   - The patient had a trial of metformin (IR/ER), a sulfonylurea (e.g., glipizide, glimepiride), pioglitazone, or a preferred combination product containing any of the above agents (e.g., glipizide-metformin, pioglitazone-metformin)
   - The patient had a trial of a preferred GLP-1 agonist (e.g., Byetta [exenatide], Bydureon [exenatide microspheres], Victoza [liraglutide])
   - Adlyxin will NOT be used concurrently with a DPP-4 inhibitor (e.g., Januvia [sitagliptin], Nesina [alogliptin], Onglyza [saxagliptin])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LIXISENATIDE (Adlyxin)** requires the following rule(s) be met for approval:
   A. You have type 2 diabetes (a disorder with high blood sugar)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), family practice, internal medicine, or another healthcare provider who specializes in diabetic management
   D. You have tried metformin (immediate-release/extended-release), a sulfonylurea (such as glipizide, glimepiride), pioglitazone, or a preferred combination product containing any of the above medications (such as glipizide-metformin, pioglitazone-metformin)
   E. You have tried a preferred GLP-1 agonist (such as Byetta [exenatide], Bydureon [exenatide microspheres], Victoza [liraglutide])

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

F. You will NOT use Adlyxin concurrently (at the same time) with a DPP-4 (dipeptidyl peptidase-4) inhibitor (such as Januvia [sitagliptin], Nesina [alogliptin], Onglyza [saxagliptin])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LIXISENATIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of type 2 diabetes (ICD-10 Groups E08, E09, E11, E13) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist, cardiologist, nephrologist, family practice, internal medicine, or another healthcare provider who specializes in diabetic management
   - Adlyxin will NOT be used concurrently with a DPP-4 inhibitor (e.g., Januvia [sitagliptin], Nesina [alogliptin], Onglyza [saxagliptin])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LIXISENATIDE (Adlyxin)** requires the following rule(s) be met for approval:
   A. You have type 2 diabetes (a disorder with high blood sugar)
   B. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), family practice, internal medicine, or another healthcare provider who specializes in diabetic management
   C. You will NOT use Adlyxin concurrently (at the same time) with a DPP-4 (dipeptidyl peptidase-4) inhibitor (such as Januvia [sitagliptin], Nesina [alogliptin], Onglyza [saxagliptin])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Adlyxin.

REFERENCES
Adlyxin [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC, September 2023.

Created: 11/22
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOFEXIDINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOFEXIDINE HCL	LUCEMYRA, LOFEXIDINE HCL	07803		GPI-10 (6280504510)	

GUIDELINES FOR USE

1. Is the requested medication being used to mitigate opioid withdrawal symptoms to facilitate abrupt opioid discontinuation (ICD-10 Group F11) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in a setting with close monitoring of treatment with Lucemyra (lofexidine) and has a treatment duration that does NOT exceed 18 days
   - Lucemyra will be administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (e.g., stool softeners, sleep aids) and the implementation of psychosocial support to help prevent relapse

   If yes, **approve for 1 fill by HICL or GPI-10 with a quantity limit of #264 per 18 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline name **LOFEXIDINE (Lucemyra)** requires the following rule(s) be met for approval:
   A. Lucemyra will be used to reduce opioid withdrawal symptoms to help abrupt opioid discontinuation
   B. You are 18 years of age or older
   C. You are in a setting with close monitoring of Lucemyra (lofexidine) treatment and will be treated with Lucemyra (lofexidine) for a maximum of 18 days
   D. Lucemyra will be used as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (such as stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LOFEXIDINE

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Lucemyra.

REFERENCES

Lucemyra [Prescribing Information]. Louisville, KY. US WorldMeds, LLC; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Created: 08/18
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOMITAPIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOMITAPIDE MESYLATE	JUXTAPID	39883		GPI-10 (3948005020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) (ICD-10 E78.01) and meet **ONE** of the following criteria?
   - The patient has a Simon Broome diagnostic criteria (definite)
   - The patient has a Dutch Lipid Network criteria with a score of at least 8
   - The patient has a clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL and either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist
   - The patient has an LDL-cholesterol level of at least 70 mg/dL while on maximally tolerated drug treatment
   - The patient had a trial of or contraindication to the clinical standard of care agent: Zetia (ezetimibe)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   - Given that the patient cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), the patient is currently taking a maximally tolerated dose of any statin

   If yes, continue to #4.
   If no, continue to #5.

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LOMITAPIDE

INITIAL CRITERIA (CONTINUED)

4. Will the patient continue statin treatment as described above in combination with Juxtapid?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has complete statin intolerance (defined by severe and intolerable adverse effects) (e.g., creatine kinase elevation at least 10 times the upper limit of normal, liver function test elevation at least 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least TWO separate statins AND have improved with the discontinuation of each statin

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to the preferred agent: Repatha (evolocumab)
   - The patient lacks functioning LDL receptors

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2mg: #1 per day.**
   - **5mg: #1 per day.**
   - **10mg: #1 per day.**
   - **20mg: #2 per day.**
   - **30mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LOMITAPIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LOMITAPIDE (Juxtapid)** requires the following rule(s) be met for approval:

A. You have homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
B. Your diagnosis is determined by meeting ONE of the following:
    1. You have Simon Broome diagnostic criteria (definite) (a tool for diagnosing homozygous familial hypercholesterolemia)
    2. You have a Dutch Lipid Network (a tool for diagnosing homozygous familial hypercholesterolemia) criteria with a score of at least 8
    3. You have a clinical diagnosis based on a history of an untreated low density lipoprotein - cholesterol (LDL-C: bad cholesterol) level greater than 500 mg/dL AND you have either xanthoma (a type of skin condition) before 10 years of age or there is evidence of heterozygous familial hypercholesterolemia (HeFH: type of inherited high cholesterol) in both parents
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), endocrinologist (a type of hormone doctor), or lipidologist (a type of cholesterol doctor)
D. You have a low density lipoprotein cholesterol (LDL-C: bad cholesterol) level of at least 70 mg/dL while on maximally tolerated statin (medication used for cholesterol) treatment
E. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: Zetia (ezetimibe)
F. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Repatha (evolocumab)
    2. You do NOT have functional LDL (low-density lipoprotein) receptors
G. If you are statin tolerant, approval also requires:
    1. You meet ONE of the following:
        a. You are currently taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
        b. You did not tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily), but you are currently taking a maximally tolerated dose of any statin
    2. You will continue statin (medication used for cholesterol) treatment in combination with Juxtapid

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LOMITAPIDE

INITIAL CRITERIA (CONTINUED)

H. If you are statin intolerant, approval also requires ONE of the following:

1. You have an absolute contraindication to (harmful for you to use) statin therapy (medication used for cholesterol) (such as active decompensated liver disease [symptoms related to liver damage], nursing [breastfeeding] female, pregnancy or plans to become pregnant, hypersensitivity [allergic] reaction)
2. You have complete statin (medication used for cholesterol) intolerance (defined by severe and intolerable adverse effects) that have occurred with trials of at least TWO separate statins, AND the adverse effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation at least 10 times the upper limit of normal, liver function test elevation at least 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

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LOMITAPIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) (ICD-10 E78.01) **AND** meet the following criterion?
   - The patient's low-density lipoprotein-cholesterol (LDL-C) level has decreased while on Juxtapid

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has continued concurrent therapy with a maximally tolerated dose of ANY statin
   - The patient has an absolute contraindication to statin therapy
   - The patient has complete statin intolerance

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2mg: #1 per day.**
   - **5mg: #1 per day.**
   - **10mg: #1 per day.**
   - **20mg: #2 per day.**
   - **30mg: #2 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOMITAPIDE (Juxtapid)** requires the following rule(s) be met for renewal:
   A. You have homozygous familial hypercholesterolemia (HoFH: type of inherited high cholesterol)
   B. Your low-density lipoprotein-cholesterol (LDL-C: bad cholesterol) level has decreased while on Juxtapid
   C. You meet ONE of the following:
      1. You have continued to take a maximally tolerated dose of ANY statin (medication used for cholesterol) along with Juxtapid
      2. You have an absolute contraindication to (harmful for you to use) statin (medication used for cholesterol) therapy
      3. You have complete statin (medication used for cholesterol) intolerance (severe and intolerable adverse effects)

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LOMITAPIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Juxtapid.

REFERENCES

Juxtapid [Prescribing Information]. Parma, Italy: Chiesi Farmaceutici S.p.A.; February 2026.

Created: 01/13
Effective: 03/28/26 Client Approval: 03/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOMUSTINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOMUSTINE	GLEOSTINE, LOMUSTINE	03900		GPI-10 (2110202000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Hodgkin's lymphoma (ICD-10 Group C81)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of primary and metastatic brain tumors (ICD-10 Group C71) and meet **ALL** of the following criteria?
   - The patient has previously received appropriate surgical and/or radiotherapeutic procedures
   - The requested medication will be used as a part of the PCV (procarbazine, lomustine, and vincristine) regimen

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOMUSTINE (Gleostine)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Hodgkin's lymphoma (a type of blood cancer)
      2. Primary and metastatic brain tumors (cancer that has spread to other parts of the body)

   B. If you have primary and metastatic brain tumors, approval also requires:
      1. You have previously received appropriate surgical and/or radiotherapeutic procedures
      2. The requested medication will be used as a part of the PCV (procarbazine, lomustine, and vincristine) regimen

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gleostine.

REFERENCES

Gleostine [Prescribing Information]. NextSource Pharma: Pompano Beach, FL; January 2024.

Created: 02/18
Effective: 12/08/25 Client Approval: 11/25 P&T Approval: 01/18

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LONAFARNIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONAFARNIB	ZOKINVY	46991		GPI-10 (9946304500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Hutchinson-Gilford Progeria Syndrome (HGPS) (ICD-10 E34.8) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a body surface area (BSA) of at least 0.39m(2)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of processing-deficient Progeroid Laminopathies and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a body surface area (BSA) of at least 0.39m(2)
   - The patient has a heterozygous LMNA mutation with progerin-like protein accumulation OR homozygous or compound heterozygous ZMPSTE24 mutations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LONAFARNIB (Zokinvy)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Hutchinson-Gilford Progeria Syndrome (HGPS: a rare genetic disorder)
      2. Processing-deficient Progeroid Laminopathies (a rare genetic disorder)

   B. If you have Hutchinson-Gilford Progeria Syndrome, approval also requires:
      1. You are 1 year of age or older
      2. You have a body surface area (BSA) of at least 0.39 meters squared

   C. If you have processing-deficient Progeroid Laminopathies, approval also requires:
      1. You are 1 year of age or older
      2. You have a body surface area (BSA) of at least 0.39 meters squared
      3. You have a heterozygous LMNA mutation (abnormal change in a type of gene) with progerin-like protein accumulation, OR you have homozygous or compound heterozygous ZMPSTE24 mutations (abnormal changes in a type of gene)

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LONAFARNIB

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zokinvy.

REFERENCES

Zokinvy [Prescribing Information]. Palo Alto, CA: Eiger BioPharmaceuticals, Inc.; March 2024.

Created: 02/21
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONAPEGSOMATROPIN-TCGD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONAPEGSOMATROPIN-TCGD	SKYTROFA	47565		GPI-10 (3010000380)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Skytrofa will NOT be used concurrently with Increlex (mecasermin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity that is less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 13.3mg: #4 per 28 days.**
   - **7.6mg, 9.1mg, 11mg: #8 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD

INITIAL CRITERIA (CONTINUED)

4. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 Group E34.3, E23.0), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Skytrofa will NOT be used concurrently with Increlex (mecasermin)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the patient's GHD caused by a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
   If no, continue to #6.

6. Is the patient's GHD confirmed by **ONE** of the following growth hormone stimulation tests?
   - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
   - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
   - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   2. You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
   1. You are 1 to 17 years of age
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed, as confirmed by a radiograph (type of imaging test) of the wrist and hand
   4. You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)
   5. You meet ONE of the following:
      a. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
      b. Your height velocity is less than the 25th percentile for your age
      c. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) for your age and gender

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LONAPEGSOMATROPIN-TCGD

INITIAL CRITERIA (CONTINUED)

C. If you are an adult patient with growth hormone deficiency, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
3. You meet ONE of the following:
   a. Your diagnosis is caused by a congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests (tests that measure the body's ability to produce growth hormone):
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
4. You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)

D. Request for Skytrofa will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), OR the patient has not completed prepubertal growth
   - Skytrofa will NOT be used concurrently with Increlex (mecasermin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **3mg, 3.6mg, 4.3mg, 5.2mg, 6.3mg, 13.3mg: #4 per 28 days.**
   - **7.6mg, 9.1mg, 11mg: #8 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA (CONTINUED)

4. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 Group E34.3, E23.0), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has achieved or maintained a response to therapy as evidenced by clinical treatment goals (e.g., improved body composition, lipid panel, bone health)
   - Skytrofa will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LONAPEGSOMATROPIN-TCGD (Skytrofa)** requires the following rule(s) be met for renewal:

   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)

   B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
      1. You are 1 to 17 years of age
      2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
      3. Your epiphyses (end part of long bone) are NOT closed, as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
      4. You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)
      5. You meet ONE of the following:
         a. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
         b. Your annual growth velocity (rate of growth) is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty

   (Renewal denial text continued on next page)

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LONAPEGSOMATROPIN-TCGD

RENEWAL CRITERIA (CONTINUED)

C. If you are an adult patient with growth hormone deficiency, renewal also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (type of hormone doctor)
3. You have achieved or maintained a response to therapy as evidenced by clinical treatment goals (such as improved body composition, lipid [fat] panel, bone health)
4. You will NOT use Skytrofa concurrently (at the same time) with Increlex (mecasermin)

D. Request for Skytrofa will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Skytrofa.

REFERENCES
Skytrofa [Prescribing Information]. Princeton, NJ: Ascendis Pharma Endocrinology, Inc.; July 2025.

Created: 10/21
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LONCASTUXIMAB TESIRINE-LPYL (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LONCASTUXIMAB TESIRINE-LPYL	ZYNLONTA	47312		GPI-10 (2135164050)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL), DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient previously received two or more lines of systemic therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LONCASTUXIMAB TESIRINE-LPYL (Zynlonta)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory large B-cell lymphoma (type of white blood cell cancer that has returned or is not responding to treatment), including diffuse large B-cell lymphoma (DLBCL), DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma
   B. You are 18 years of age or older
   C. You previously received two or more lines of systemic therapy (treatment that travels throughout the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zynlonta.

REFERENCES

Zynlonta [Prescribing Information]. Epalinges, Switzerland: ADC Therapeutics SA, April 2021.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/01/21
Created: 07/21
Client Approval 08/21
P&T Approval: 07/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LORLATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LORLATINIB	LORBRENA	45448		GPI-10 (2153055600)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors are anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test
   - The patient had a trial of or contraindication to ONE of the following first-line preferred agents: Alecensa (alectinib), Alunbrig (brigatinib)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **25mg: #3 per day.**
   - **100mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LORLATINIB (Lorbrena)** requires the following rule(s) be met for approval:
   A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors are anaplastic lymphoma kinase (ALK: a type of enzyme)-positive, as detected by a Food and Drug Administration (FDA)-approved test
   D. You have tried or have a contraindication to (harmful for you to use) ONE of the following first-line preferred medications: Alecensa (alectinib), Alunbrig (brigatinib)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lorbrena.

REFERENCES

Lorbrena [Prescribing Information]. New York, NY: Pfizer, Inc.; February 2024.

Created: 03/19
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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LOSARTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOSARTAN POTASSIUM	ARBLI	09829		GPI-10 (3615004020)	BRAND = ARBLI

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypertension (ICD-10 I10) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow losartan tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of hypertension (ICD-10 I10) with left ventricular hypertrophy (ICD-10 I51.7) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow losartan tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of type 2 diabetes with diabetic nephropathy (ICD-10 E11.21) and meet **ALL** of the following criteria?
   - The patient has a history of hypertension
   - The patient has an elevated serum creatinine level and proteinuria (urinary albumin to creatinine ratio of at least 300mg/g)
   - The patient has a contraindication to or is unable to swallow losartan tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LOSARTAN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LOSARTAN (Arbli)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hypertension (high blood pressure)
   2. Hypertension with left ventricular hypertrophy (a type of heart condition)
   3. Type 2 diabetes (a disorder with high blood sugar) with diabetic nephropathy (a type of kidney disease caused by high blood sugar)

B. If you have hypertension, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow losartan tablets

C. If you have hypertension with left ventricular hypertrophy, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow losartan tablets

D. If you have type 2 diabetes with diabetic nephropathy, approval also requires:
   1. You have a history of hypertension (high blood pressure)
   2. You have an elevated serum creatinine (a type of lab test to measure kidney function) level and proteinuria (a condition with high levels of protein in the urine) (urinary albumin to creatinine ratio of at least 300mg/g)
   3. You have a contraindication to (harmful for you to use) or are unable to swallow losartan tablets

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arbli.

REFERENCES

Arbli [Prescribing Information]. Commack, NY: Scienture LLC; March 2025.

Created: 06/25
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LOTILANER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LOTILANER	XDEMVY	45544		GPI-10 (8610605000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Demodex blepharitis (ICD-10 Group H01.00) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 6 weeks by HICL or GPI-10 with a quantity limit of #10mL for 1 fill.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LOTILANER (Xdemvy)** requires the following rule(s) be met for approval:
   A. You have Demodex blepharitis (a type of inflammatory eye condition)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xdemvy.

REFERENCES

Xdemvy [Prescribing Information]. Irvine, CA: Tarsus Pharmaceuticals, Inc.; July 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 10/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LU-177 VIPIVOTIDE TETRAXETAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LU-177 VIPIVOTIDE TETRAXETAN	PLUVICTO	47914		GPI-10 (2160004580)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2 and C61) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is prostate-specific membrane antigen (PSMA)-positive
   - The patient has been treated with androgen receptor pathway inhibitor (ARPI) therapy (e.g., enzalutamide, abiraterone)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - It is appropriate to delay taxane-based chemotherapy (e.g., docetaxel, cabazitaxel)
   - The patient has received prior taxane-based chemotherapy (e.g., docetaxel, cabazitaxel)

   If yes, **approve for 12 months by HICL or GPI-10 for 6 fills.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LU-177 VIPIVOTIDE TETRAXETAN (Pluvicto)** requires the following rule(s) be met for approval:
   A. You have metastatic castration-resistant prostate cancer (mCRPC: a type of prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
   B. You are 18 years of age or older
   C. Your cancer is prostate-specific membrane antigen (PSMA)-positive (a type of test)
   D. You have been treated with androgen receptor pathway inhibitor (ARPI) therapy (such as enzalutamide, abiraterone)
   E. You meet ONE of the following:
      1. It is appropriate to delay taxane-based chemotherapy (medications used to treat cancer such as docetaxel, cabazitaxel)
      2. You have received prior taxane-based chemotherapy

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LU-177 VIPIVOTIDE TETRAXETAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pluvicto.

REFERENCES

Pluvicto [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2025.

Created: 05/22
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUMACAFTOR-IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUMACAFTOR/IVACAFTOR	ORKAMBI	42235		GPI-10 (4530990230)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Orkambi will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient is homozygous for the F508del mutation in the CFTR gene

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   - **75-94mg granule packets: #2 per day.**
   - **100-125mg granule packets: #2 per day.**
   - **150-188mg granule packets: #2 per day.**
   - **100-125mg tablets: #4 per day.**
   - **200-125mg tablets: #4 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You are 1 year of age or older
   C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
   D. You will NOT use Orkambi concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   E. You are homozygous (have two copies of the same gene) for the F508del mutation (abnormal change) in the CFTR gene

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUMACAFTOR-IVACAFTOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Orkambi will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by GPID or GPI-14 for all of the following:**
   - **75-94mg granule packets: #2 per day.**
   - **100-125mg granule packets: #2 per day.**
   - **150-188mg granule packets: #2 per day.**
   - **100-125mg tablets: #4 per day.**
   - **200-125mg tablets: #4 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Orkambi concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orkambi.

REFERENCES

Orkambi [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; December 2024.

Created: 07/15
Effective: 02/10/25 Client Approval: 01/25 P&T Approval: 01/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUMASIRAN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUMASIRAN SODIUM	OXLUMO	46999		GPI-10 (5662604020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary hyperoxaluria type 1 (PH1)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUMASIRAN (Oxlumo)** requires the following rule(s) be met for approval:
   A. You have primary hyperoxaluria type 1 (PH1: a rare disorder in which buildup of a substance called oxalate is deposited in the kidneys and urinary tract)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oxlumo.

REFERENCES

Oxlumo [Prescribing Information]. Cambridge, MA: Alynlam Pharmaceuticals, Inc.; November 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/01/21
Created: 02/21
Client Approval:02/21
P&T Approval: 01/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LURBINECTEDIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LURBINECTEDIN	ZEPZELCA	46626		GPI-10 (2110002400)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of small cell lung cancer (SCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have extensive-stage small cell lung cancer (ES-SCLC) and meet **ALL** of the following criteria?
   - Zepzelca will be used in combination with Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs)
   - The patient's disease has not progressed after first-line induction therapy with Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), carboplatin, and etoposide

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient's cancer metastatic **AND** the patient meets the following criterion?
   - The patient had disease progression on or after platinum-based chemotherapy (e.g. carboplatin, cisplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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LURBINECTEDIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LURBINECTEDIN (Zepzelca)** requires the following rule(s) be met for approval:

A. You have small cell lung cancer (SCLC: a type of lung cancer)
B. You are 18 years of age or older
C. You meet ONE of the following:
   1. You have extensive-stage small cell lung cancer (ES-SCLC: a type of lung cancer); Zepzelca will be used in combination with Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs); AND your disease has not progressed (worsened) after first-line induction therapy (start of treatment) with Tecentriq (atezolizumab) or Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs), carboplatin, and etoposide
   2. Your cancer is metastatic (has spread to other parts of the body); AND you had disease progression (worsening) on or after platinum-based chemotherapy (a type of cancer treatment such as carboplatin or cisplatin)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zepzelca.

REFERENCES

Zepzelca [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc., October 2025.

Created: 07/20
Effective: 11/03/25 Client Approval: 10/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUSPATERCEPT-AAMT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUSPATERCEPT-AAMT	REBLOZYL	46196		GPI-10 (8240054010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of beta thalassemia (ICD-10 D56.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient requires regular red blood cell (RBC) transfusions
   - Reblozyl will be used for the treatment of anemia

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of very low- to intermediate-risk myelodysplastic syndrome (MDS) (ICD-10 Group D46) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is erythropoiesis stimulating agent (ESA)-naïve (has not previously used an ESA such as Epogen [epoetin alfa])
   - Reblozyl will be used for the treatment of anemia

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have **ONE** of the following diagnoses?
   - Very low- to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS) (ICD-10 D46.B, D46.1)
   - Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) (ICD-10 D46.B and D46.1 and D47.1 and Group D75.83)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is failing an erythropoiesis stimulating agent (ESA) (e.g., Epogen [epoetin alfa]) AND requires at least 2 red blood cell (RBC) units over 8 weeks
   - Reblozyl will be used for the treatment of anemia

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUSPATERCEPT-AAMT
CONTINUED ON NEXT PAGE

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LUSPATERCEPT-AAMT

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **LUSPATERCEPT-AAMT (Reblozyl)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Beta thalassemia (a type of blood condition)
   2. Very low- to intermediate-risk myelodysplastic syndrome (MDS: a type of blood cancer)
   3. Very low- to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS: a type of blood cancer)
   4. Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T: a type of blood cancer)

B. If you have beta thalassemia, approval also requires:
   1. You are 18 years of age or older
   2. You require regular red blood cell (RBC) transfusions (adding blood to your body)
   3. Reblozyl will be used for the treatment of anemia (a type of blood condition)

C. If you have very low- to intermediate-risk myelodysplastic syndrome, approval also requires:
   1. You are 18 years of age or older
   2. You are erythropoiesis stimulating agent (ESA)-naïve (you have not previously used a type of medication that increases the production of red blood cells such as Epogen [epoetin alfa])
   3. Reblozyl will be used for the treatment of anemia (a type of blood condition)

D. If you have very low- to intermediate-risk myelodysplastic syndrome with ring sideroblasts OR with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis, approval also requires:
   1. You are 18 years of age or older
   2. You are failing an erythropoiesis stimulating agent (ESA: a type of medication that increases the production of red blood cells, such as Epogen [epoetin alfa])
   3. You require at least 2 red blood cell (RBC) units over 8 weeks
   4. Reblozyl will be used for the treatment of anemia (a type of blood condition)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Reblozyl.

REFERENCES

Reblozyl [Prescribing Information]. Summit, NJ: Celgene Corporation; May 2024.

Created: 02/20
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUSUTROMBOPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUSUTROMBOPAG	MULPLETA	45127		GPI-10 (8240504500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of thrombocytopenia (ICD-10 D69.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has chronic liver disease
   - The patient is scheduled to undergo a procedure 8 to 14 days after starting Mulpleta (lusutrombopag) therapy
   - Therapy is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, endocrinologist, or surgeon
   - The patient has a platelet count of less than 50x10^9 cells/L measured within the last 30 days
   - Mulpleta will NOT be used concurrently with other thrombopoietin receptor agonists [TPO-RAs] (e.g., Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag])

   If yes, **approve for 1 fill by HICL or GPI-10 with a quantity limit of #7 tablets.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUSUTROMBOPAG (Mulpleta)** requires the following rule(s) be met for approval:
   A. You have thrombocytopenia (a type of blood disorder)
   B. You are 18 years of age or older
   C. You have chronic (long-term) liver disease
   D. You are scheduled to undergo a procedure 8 to 14 days after starting Mulpleta (lusutrombopag) therapy
   E. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor), gastroenterologist (a type of doctor who treats digestive conditions), hepatologist (a type of liver doctor), immunologist (a type of immune system doctor), endocrinologist (a type of hormone doctor), or surgeon
   F. You have a platelet count of less than 50x10^9 cells/L measured within the last 30 days
   G. You will NOT use Mulpleta concurrently (at the same time) with other thrombopoietin receptor agonists [TPO-RAs] (such as Doptelet [avatrombopag], Nplate [romiplostim], Promacta [eltrombopag])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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LUSUTROMBOPAG

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mulpleta.

REFERENCES

Mulpleta [Prescribing Information]. Florham Park, NJ: Shionogi & Co, Ltd.; April 2020.

Created: 11/18
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/22

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUTETIUM LU 177 DOTATATE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUTETIUM LU 177 DOTATATE	LUTATHERA	44750		GPI-10 (2160004520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, or hindgut neuroendocrine tumors, and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Lutathera will be used in combination with a long-acting octreotide (e.g., Sandostatin LAR Depot [octreotide]) as maintenance therapy
   - The patient has previously been treated with a long-acting somatostatin analog (e.g., octreotide, lanreotide) prior to the request of Lutathera
   - The patient has NOT received a total of 4 doses of Lutathera per lifetime

   If yes, **approve for 8 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **LUTETIUM LU 177 DOTATATE (Lutathera)** requires the following rule(s) be met for approval:
   A. You have somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs: type of hormone cancer in digestive tract), which includes foregut, midgut, or hindgut neuroendocrine tumors
   B. You are 12 years of age or older
   C. Lutathera will be used together with a long-acting octreotide (such as Sandostatin LAR Depot [octreotide]) as maintenance therapy
   D. You have previously been treated with a long-acting somatostatin analog (such as octreotide, lanreotide) before the request for Lutathera
   E. You have NOT received a total of 4 doses of Lutathera in your lifetime

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUTETIUM LU 177 DOTATATE (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lutathera.

REFERENCES

Lutathera [Prescribing Information]. New York, NY: Advanced Accelerator Applications USA, Inc.; April 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 05/17/24
Created: 05/18
Client Approval: 05/24
P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MACITENTAN	OPSUMIT, MACITENTAN	40677		GPI-10 (4016005000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN (Opsumit)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   C. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN (Opsumit)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opsumit.

REFERENCES

Opsumit [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; April 2025.

Created: 10/22
Effective: 06/06/26 Client Approval: 06/26 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN-TADALAFIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MACITENTAN/ TADALAFIL	OPSYNVI	47644		GPI-10 (4099550250)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has WHO Functional Class II-III symptoms
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Opsynvi will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Opsynvi will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You are 18 years of age or older
   (*Initial denial text continued on the next page)*

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MACITENTAN-TADALAFIL

INITIAL CRITERIA (CONTINUED)

C. You have WHO Functional Class II-III symptoms (a way to classify how limited physical activity)
D. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
E. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension) greater than 2 Wood units
F. You will NOT use Opsynvi concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
G. You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN-TADALAFIL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - Opsynvi will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - Opsynvi will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MACITENTAN-TADALAFIL (Opsynvi)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   B. You will NOT use Opsynvi concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use Opsynvi concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opsynvi.

REFERENCES

Opsynvi [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 04/24
Client Approval: 06/24
P&T Approval: 04/24

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MARALIXIBAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARALIXIBAT CHLORIDE	LIVMARLI	47604		GPI-10 (5235005010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cholestatic pruritus (ICD-10 L29.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's cholestatic pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and the patient meets **ALL** of the following criteria?
   - The patient is 3 months of age or older
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in ALGS cholestasis
   - Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve all strengths and formulations for 6 months by GPID or GPI-14 as follows:**
   - **9.5mg/mL oral solution: #3mL per day.**
   - **10mg, 15mg, 20mg, 30mg tablet: #1 per day.**

   If no, continue to #3.

3. Is the patient's cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and the patient meets **ALL** of the following criteria?
   - The patient is 12 months of age or older
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in PFIC cholestasis
   - Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve all strengths and formulations for 6 months by GPID or GPI-14 as follows:**
   - **19mg/mL oral solution: #2mL per day.**
   - **10mg, 15mg, 20mg tablet: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

B. If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:
   1. You are 3 months of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in ALGS cholestasis
   3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

C. If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:
   1. You are 12 months of age or older
   2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
   3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MARALIXIBAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cholestatic pruritus (ICD-10 L29.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient's cholestatic pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and the patient meets **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline
   - Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve the requested formulation for 12 months by GPID or GPI-14 as follows:**
   - **9.5mg/mL oral solution: #3mL per day.**
   - **10mg, 15mg, 20mg, 30mg tablet: Approve all strengths with a quantity limit of #1 per day.**

   If no, continue to #3.

3. Is the patient's cholestatic pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and the patient meets **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline
   - The patient does NOT have PFIC type 2 with specific ABCB11 variants that would result in nonfunctional, or the complete absence of, bile salt export pump (BSEP) protein
   - Livmarli will NOT be used concurrently with another IBAT inhibitor (e.g., Bylvay [odevixibat])

   If yes, **approve the requested formulation for 12 months by GPID or GPI-14 as follows:**
   - **19mg/mL oral solution: #2mL per day.**
   - **10mg, 15mg, 20mg tablet: Approve all strengths with a quantity limit of #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MARALIXIBAT (Livmarli)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)

B. If you have cholestatic pruritus associated with Alagille syndrome, renewal also requires:
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Livmarli)
   2. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

C. If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, renewal also requires:
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Livmarli)
   2. You do NOT have PFIC type 2 with specific ABCB11 variants (a type of abnormal gene) that would result in nonfunctional (does not work), or the complete absence of, bile salt export pump (BSEP: a type of protein)
   3. You will NOT use Livmarli concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Bylvay [odevixibat])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Livmarli.

REFERENCES

Livmarli [Prescribing Information]. Foster City, CA: Mirum Pharmaceuticals, Inc.; April 2025.

Created: 10/21
Effective: 06/01/25 Client Approval: 05/25 P&T Approval: 10/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MARGETUXIMAB-CMKB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARGETUXIMAB-CMKB	MARGENZA	47037		GPI-10 (2117003420)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic HER2-positive breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Margenza will be used in combination with chemotherapy (e.g., Xeloda, Halaven, gemcitabine, Navelbine)
   - The patient has received two or more prior anti-HER2 regimens (e.g., Herceptin, Perjeta), at least one of which was for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 fill per 21 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARGETUXIMAB-CMKB (Margenza)** requires the following rule(s) be met for approval:
   A. You have metastatic (cancer has spread to other parts of the body) HER2 (human epidermal growth factor receptor 2: type of protein found in breast cancer)-positive breast cancer
   B. You are 18 years of age or older
   C. Margenza will be used in combination with chemotherapy (such as Xeloda, Halaven, gemcitabine, Navelbine)
   D. You have received two or more prior anti-HER2 regimens (such as Herceptin, Perjeta), at least one of which was for metastatic disease

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MARGETUXIMAB-CMKB (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Margenza.

REFERENCES

Margenza [Prescribing Information]. Rockville, MD: MacroGenics, Inc.; December 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 05/21
Client Approval: 05/21
P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MARIBAVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARIBAVIR	LIVTENCITY	47687		GPI-10 (1220005000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a post-transplant cytomegalovirus (CMV) infection (ICD-10 Group B25) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The infection is refractory to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet
   - Therapy is prescribed by or in consultation with a transplant specialist or infectious disease specialist

   If yes, **approve for 8 weeks by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARIBAVIR (Livtencity)** requires the following rule(s) be met for approval:
   A. You have a post-transplant cytomegalovirus (CMV) infection (a type of viral infection)
   B. You are 12 years of age or older
   C. Your infection is refractory (has not responded) to prior therapy with ganciclovir, valganciclovir, cidofovir or foscarnet
   D. Therapy is prescribed by or in consultation with a transplant specialist or infectious disease specialist (a doctor who specializes in the treatment of infections)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Livtencity.

REFERENCES

Livtencity [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; March 2024.

Created: 12/21
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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MARSTACIMAB-HNCQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MARSTACIMAB-HNCQ	HYMPAVZI	49937		GPI-10 (8510505020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   - Hympavzi will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh])

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **150mg/mL: #8mL per 28 days.**
   - **75mg/0.5 mL: #2.5mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of hemophilia B (congenital factor IX deficiency) (ICD-10 D67) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   - Hympavzi will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh])

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **150mg/mL: #8mL per 28 days.**
   - **75mg/0.5mL: #2.5mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MARSTACIMAB-HNCQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MARSTACIMAB-HNCQ (Hympavzi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   2. Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

B. If you have hemophilia A (congenital factor VIII deficiency), approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   4. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

C. If you have hemophilia B (congenital factor IX deficiency), approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. Hympavzi will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   4. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

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MARSTACIMAB-HNCQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) (ICD-10 Z14.0) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline
   - Hympavzi will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh])

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **150mg/mL: #8mL per 28 days.**
   - **75mg/0.5 mL: #2.5mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of hemophilia B (congenital factor IX deficiency) (ICD-10 D67) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline
   - Hympavzi will NOT be used concurrently with another non-factor prophylaxis therapy (e.g., Hemlibra [emicizumab-kxwh])

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **150mg/mL: #8mL per 28 days.**
   - **75mg/0.5 mL: #2.5mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MARSTACIMAB-HNCQ (Hympavzi)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
      2. Hemophilia B (congenital factor IX deficiency: a type of bleeding disorder)

   B. If you have hemophilia A (congenital factor VIII deficiency), renewal also requires:
      1. You have shown a clinical benefit compared to baseline (before starting Hympavzi)
      2. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

   C. If you have hemophilia B (congenital factor IX deficiency), renewal also requires:
      1. You have shown a clinical benefit compared to baseline (before starting Hympavzi)
      2. You will NOT use Hympavzi concurrently (at the same time) with another non-factor prophylaxis therapy (such as Hemlibra [emicizumab-kxwh])

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MARSTACIMAB-HNCQ

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Hympavzi.

REFERENCES
Hympavzi [Prescribing Information]. New York, NY: Pfizer Inc.; June 2026.

Created: 11/24
Effective: 07/04/26 Client Approval: 07/26 DMC Approval: 06/30/26

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MAVACAMTEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MAVACAMTEN	CAMZYOS	47972		GPI-10 (4019005000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) (ICD-10 I42.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist
   - The patient has New York Heart Association (NYHA) functional class II or III
   - The patient has a peak left ventricular outflow tract (LVOT) gradient of at least 50 mmHg at rest or with provocation
   - Camzyos will NOT be used concurrently with another myosin inhibitor (e.g., Myqorzo [aficamten]) for the treatment of hypertrophic cardiomyopathy
   - The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: a beta-blocker (e.g., metoprolol, carvedilol), a non-dihydropyridine calcium channel blocker (e.g., verapamil, diltiazem)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MAVACAMTEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for approval:

A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
D. You have New York Heart Association (NYHA) functional class II or III (a way to classify the severity of symptoms)
E. You have a peak left ventricular outflow tract (LVOT) gradient (evaluates the severity of disease) of at least 50 mmHg at rest or with provocation (a type of technique to evaluate how the heart performs under stress)
F. You will NOT use Camzyos concurrently (at the same time) with another myosin inhibitor (such as Myqorzo [aficamten]) for the treatment of hypertrophic cardiomyopathy (a type of heart condition)
G. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a beta-blocker (such as metoprolol, carvedilol), a non-dihydropyridine calcium channel blocker (such as verapamil, diltiazem)

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MAVACAMTEN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (HCM) (ICD-10 I42.1) and meet **ALL** of the following criteria?
   - The patient has experienced continued clinical benefit (e.g., reduction of symptoms, NYHA classification improvement)
   - Camzyos will NOT be used concurrently with another myosin inhibitor (e.g., Myqorzo [aficamten]) for the treatment of hypertrophic cardiomyopathy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MAVACAMTEN (Camzyos)** requires the following rule(s) be met for renewal:
   A. You have symptomatic obstructive hypertrophic cardiomyopathy (HCM: a type of heart condition)
   B. You have experienced continued clinical benefit (such as reduction of symptoms, New York Heart Association [NYHA] classification [a way to classify severity of symptoms] improvement)
   C. You will NOT use Camzyos concurrently (at the same time) with another myosin inhibitor (such as Myqorzo [aficamten]) for the treatment of hypertrophic cardiomyopathy (a type of heart condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Camzyos.

REFERENCES

Camzyos [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; April 2025.

Created: 05/22
Effective:07/01/26 Client Approval: 06/26 DMC Approval: 06/16/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MAVORIXAFOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MAVORIXAFOR	XOLREMDI	49557		GPI-10 (8250204600)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MAVORIXAFOR (Xolremdi)** requires the following rule(s) be met for approval:
   A. You have WHIM (warts, hypogammaglobulinemia [low levels of antibodies in the blood], infections, and myelokathexis [low white blood cell count]) syndrome (a rare genetic disorder of the immune system)
   B. You are 12 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolremdi.

REFERENCES

Xolremdi [Prescribing Information]. Boston, MA: X4 Pharmaceuticals, Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/27/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MEBENDAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MEBENDAZOLE	EMVERM		43181	GPI-14 (15000010000505)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of *Enterobius vermicularis* (pinworm) infection (ICD-10 B80) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of or contraindication to pyrantel pamoate (OTC)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #2**.
   If no, continue to #2.

2. Does the patient have a diagnosis of *Trichuris trichiura* (whipworm) (ICD-10 B79) or *Ascaris lumbricoides* (roundworm) (ICD-10 Group B77) infection and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of or contraindication to albendazole (Albenza)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #6**.
   If no, continue to #3.

3. Does the patient have a diagnosis of *Ancylostoma duodenale* (hookworm) (ICD-10 B76.0) or *Necator americanus* (hookworm) (ICD-10 B76.1) infection and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of or contraindication to albendazole (Albenza) or pyrantel pamoate (OTC)

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #6.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MEBENDAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MEBENDAZOLE (Emverm)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. *Enterobius vermicularis* (pinworm) infection
   2. *Trichuris trichiura* (whipworm) infection
   3. *Ascaris lumbricoides* (roundworm) infection
   4. *Ancylostoma duodenale* (hookworm) infection
   5. *Necator americanus* (hookworm) infection

B. If you have *Enterobius vermicularis* (pinworm) infection, approval also requires:
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) over-the-counter (OTC) pyrantel pamoate

C. If you have Trichuris trichiura (whipworm) or Ascaris lumbricoides (roundworm) infection, approval also requires:
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) albendazole (Albenza)

D. If you have Ancylostoma duodenale (hookworm) or Necator americanus (hookworm) infection, approval also requires:
   1. You are 2 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) albendazole (Albenza) OR over-the-counter (OTC) pyrantel pamoate

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emverm.

REFERENCES

Emverm [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; August 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 03/16
Client Approval: 06/24
P&T Approval: 07/20

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MECAMYLAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECAMYLAMINE HCL	VECAMYL		1471	GPI-10 (3660002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderately severe to severe essential (primary) hypertension (ICD-10 I10) or uncomplicated malignant hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist, nephrologist, or endocrinologist
   - The patient's blood pressure is NOT controlled on at least three anti-hypertensive agents from different pharmacologic classes (e.g., an angiotensin receptor blocker [e.g., valsartan], a calcium channel blocker [e.g., amlodipine], a diuretic [e.g., hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks
   - The patient does NOT have resistant hypertension due to white coat effect, medical inertia, poor therapeutic adherence, or secondary causes of hypertension (except sleep apnea)
   - Vecamyl will be used concurrently with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses
   - The patient had a trial of or contraindication to BOTH clinical standard of care agents: a potent diuretic (clorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (spironolactone or eplerenone)

     If yes, **approve for 2 months by GPID or GPI-10.**
     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

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MECAMYLAMINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MECAMYLAMINE (Vecamyl)** requires the following rule(s) be met for approval:

A. You have moderately severe to severe essential (primary) hypertension (high blood pressure) or uncomplicated malignant hypertension (severe high blood pressure)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), nephrologist (a type of kidney doctor), or endocrinologist (a type of hormone doctor)
C. Your blood pressure is NOT controlled on at least three anti-hypertensive medications (medications used to treat high blood pressure) with different mechanisms of action (such as an angiotensin receptor blocker [such as valsartan], a calcium channel blocker [such as amlodipine], a diuretic [such as hydrochlorothiazide]) at a maximally tolerated dose for at least 4 weeks
D. You do NOT have resistant hypertension (a type of high blood pressure) due to white coat effect (a condition where blood pressure is higher in a medical setting), medical inertia (when healthcare providers do not make changes to treatment even if the medical condition is poorly controlled), poor therapeutic adherence (not keeping up with therapy), or secondary causes of hypertension (high blood pressure that is caused by another medical condition) (except sleep apnea [a type of sleep condition with difficulty breathing])
E. You will use Vecamyl concurrently (at the same time) with at least three other anti-hypertensive medications (medications used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses
F. You have tried or have a contraindication to (harmful for you to use) BOTH clinical standard of care medications: a potent diuretic (chlorthalidone or indapamide) AND a mineralocorticoid receptor antagonist (spironolactone or eplerenone)

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MECAMYLAMINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderately severe to severe essential (primary) hypertension (ICD-10 I10) or uncomplicated malignant hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - The patient continues to benefit from Vecamyl
   - Vecamyl will be used concurrently with at least three other anti-hypertensive agents (e.g., valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MECAMYLAMINE (Vecamyl)** requires the following rule(s) be met for renewal:
   A. You have moderately severe to severe essential (primary) hypertension (high blood pressure) or uncomplicated malignant hypertension (severe high blood pressure)
   B. You continue to benefit from Vecamyl
   C. You will use Vecamyl concurrently (at the same time) with at least three other anti-hypertensive medications (medications used to treat high blood pressure such as valsartan, amlodipine, hydrochlorothiazide) at maximally tolerated doses

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vecamyl.

REFERENCES

Vecamyl [Prescribing Information]. Jersey City, NJ: Tilde Sciences, LLC; July 2024.

Created: 05/13
Effective: 03/25/26 Client Approval: 03/26 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MECASERMIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECASERMIN	INCRELEX	33207		GPI-10 (3016004500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Severe primary IGF-1 deficiency (ICD-10 E34.321)
   - Growth hormone (GH) gene deletion (not growth hormone-deficient short stature) **AND** have neutralizing antibodies to GH

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 2 years to less than 18 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist or a nephrologist
   - The patient has a height standard deviation score of less than or equal to -3.0
   - The patient has a basal IGF-1 standard deviation score of less than or equal to -3.0
   - The patient has normal or elevated growth hormone (GH) (serum growth hormone level of at least 10ngm/mL to at least 2 stimuli [insulin, levodopa, arginine, clonidine, or glucagon])
   - The patient's epiphyses (bone growth plates) are open (as confirmed by radiograph of the wrist and hand)
   - Increlex will NOT be used concurrently with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline**.**

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MECASERMIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Severe primary insulin-like growth factor 1 deficiency (IGF-1: hormone levels that promote normal bone and tissue growth and development are extremely low or undetectable in the blood)
   2. Growth hormone gene deletion (not growth hormone-deficient short stature) with neutralizing antibodies to growth hormone

B. You are 2 years to less than 18 years of age

C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor) or nephrologist (a type of kidney doctor)

D. You have a height standard deviation score of less than or equal to -3.0

E. You have a basal IGF-1 (insulin-like growth factor 1) standard deviation score of less than or equal to -3.0

F. You have normal or elevated growth hormone (serum growth hormone level of at least 10ngm/mL to at least 2 stimuli [insulin, levodopa, arginine, clonidine or glucagon])

G. Your bone growth plates (epiphyses) are open (as confirmed by radiograph [a type of imaging] of the wrist and hand)

H. You will NOT use Increlex concurrently (at the same time) with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MECASERMIN

RENEWAL CRITERIA

1. Will Increlex be used concurrently with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd])?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient is near the terminal phase of puberty and has an annual growth velocity of at least 1 cm compared with what was observed from the previous year

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MECASERMIN (Increlex)** requires the following rule(s) be met for renewal:
   A. You will NOT use Increlex concurrently (at the same time) with another growth hormone medication (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Zomacton], Ngenla [somatrogon-ghla], Sogroya [somapacitan-beco], Skytrofa [lonapegsomatropin-tcgd])
   B. You meet ONE of the following:
      1. Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
      2. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MECASERMIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Increlex.

REFERENCES

Increlex [Prescribing Information]. Deer Park, IL: Eton Pharmaceuticals, Inc.; July 2025.

Created: 02/06
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MECHLORETHAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MECHLORETHAMINE HCL	VALCHLOR	03892		GPI-10 (9037105020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCL) (ICD-10 Group C84.0) **AND** meet the following criterion?
   - The patient has received prior skin-directed therapy (e.g., corticosteroids, carmustine, topical retinoids [Targretin (bexarotene), Tazorac (tazarotene)], imiquimod, local radiation therapy)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MECHLORETHAMINE (Valchlor)** requires the following rule(s) be met for approval:
   A. You have Stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCL) (a type of blood cancer that affects the skin)
   B. You have received prior skin-directed therapy (such as corticosteroids, carmustine, topical retinoids [Targretin (bexarotene), Tazorac (tazarotene)], imiquimod, local radiation therapy)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Valchlor.

REFERENCES

Valchlor [Prescribing Information]. Iselin, NJ: Helsinn Therapeutics (U.S.), Inc.; January 2020.

Created: 11/13
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 11/13

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MEPOLIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MEPOLIZUMAB	NUCALA	42775		GPI-10 (4460405500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   - The patient has a blood eosinophil level of at least 150 cells/mcL within the past 12 months
   - Nucala will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

   If yes, **approve all formulations of the requested strength for 4 months by GPID or GPI-14 as follows:**
   - **100mg: #1 per 28 days.**
   - **40mg/0.4mL: #0.4mL per 28 days.**

   If no, continue to #3.

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve all formulations of the requested strength for 4 months by GPID or GPI-14 as follows:**
   - **100mg: #1 per 28 days.**
   - **40mg/0.4mL: #0.4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease
   - The patient had a 56-day trial of ONE clinical standard of care agent: an intranasal corticosteroid (e.g., mometasone nasal spray)
   - Nucala will be used as add-on maintenance treatment
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve all formulations of the 100mg strength for 6 months by GPID or GPI-14 with a quantity limit of #1 per 28 days.**

   If no, continue to #5.

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Fasenra [benralizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

   If yes, **approve all formulations of the 100mg strength for 12 months by GPID or GPI-14 with a quantity limit of #3 per 28 days.**

   If no, continue to #6.

6. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has had HES for at least 6 months without an identifiable non-hematologic secondary cause
   - Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
   - The patient has a blood eosinophil count of at least 1000 cell/mcL at initiation of therapy
   - The patient has a negative FIP1L1-PDGFRA test
   - The patient has been stable on HES therapy (corticosteroid [e.g., prednisone]) for at least 4 weeks
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Fasenra [benralizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HES

   If yes, **approve all formulations of the 100mg strength for 8 months by GPID or GPI-14 with a quantity limit of #3 per 28 days.**

   If no, continue to #7.

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and J44.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an eosinophilic phenotype of COPD
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient has an elevated blood eosinophil count of at least 150 cell/mcL at screening (within the past 3 months) OR at least 300 cells/mcL in the previous 12 months
   - Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere)
   - Nucala will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

   If yes, **approve all formulations of the 100mg strength for 4 months by GPID or GPI-14 with a quantity limit of #1 per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
      2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
      3. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
      4. Hypereosinophilic syndrome (HES: a type of blood disorder)
      5. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

B. If you have severe asthma with an eosinophilic phenotype, approval also requires:

1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) or allergy medicine
3. You have a blood eosinophil level (a type of lab test) of at least 150 cells/mcL within the past 12 months
4. Nucala will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
5. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of lung condition with inflammation)
6. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

C. If you have chronic rhinosinusitis with nasal polyps, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
3. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
4. You have inadequately controlled disease
5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray)
6. Nucala will be used as add-on maintenance treatment (taken on a regular basis)
7. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps (inflammation of nasal and sinus passages with small growths in the nose)

D. If you have eosinophilic granulomatosis with polyangiitis, approval also requires:

1. You are 18 years of age or older
2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis (a type of immune system disorder with inflammation of blood vessels)

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

E. If you have hypereosinophilic syndrome, approval also requires:
1. You are 12 years of age or older
2. You have had hypereosinophilic syndrome (HES: a type of blood disorder) for at least 6 months without an identifiable non-hematologic (not present in the blood) secondary cause (HES is not caused by another condition)
3. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
4. You have a blood eosinophil count (a type of lab test) of at least 1000 cells/mcL at the start of therapy
5. You have a negative FIP1L1-PDFRA test (a type of lab test that detects a type of gene mutation)
6. You have been stable on hypereosinophilic syndrome (HES: a type of blood disorder) therapy (corticosteroid [such as prednisone]) for at least 4 weeks
7. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome (a type of blood disorder)

F. If you have chronic obstructive pulmonary disease, approval also requires:
1. You are 18 years of age or older
2. You have an eosinophilic phenotype of chronic obstructive pulmonary disease (COPD: a type of inflammatory long-term lung condition)
3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
4. You have an elevated blood eosinophil count (a type of lab test) of at least 150 cell/mcL at screening (within the past 3 months) OR at least 300 cells/mcL in the previous 12 months
5. Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
6. You will NOT use Nucala concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype chronic obstructive pulmonary disease (a type of long-term lung condition)

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MEPOLIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   - **100mg: #1 per 28 days.**
   - **40mg/0.4mL: #0.4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of CRSwNP

   If yes, **approve all formulations of the 100mg strength for 12 months by GPID or GPI-14 with a quantity limit of #1 per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) (ICD-10 M30.1), also known as Churg-Strauss syndrome, and meet **ALL** of the following criteria?
   - The patient has shown a reduction in EGPA symptoms compared to baseline OR has been able to reduce/eliminate corticosteroid use
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Fasenra [benralizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of EGPA

   If yes, **approve all formulations of the 100mg strength for 12 months by GPID or GPI-14 with a quantity limit of #3 per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) (ICD-10 Group J44 except for ICD-10 J44.0 and J44.81) and meet **ALL** of the following criteria?
   - The patient has an eosinophilic phenotype of COPD
   - Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (e.g., Trelegy Ellipta, Breztri Aerosphere)
   - Nucala will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype COPD

   If yes, continue to #6.
   If no, continue to #7.

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

6. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - The patient has a reduction in COPD exacerbations from baseline
   - The patient has a reduction in severity or frequency of COPD-related symptoms (e.g., wheezing, shortness of breath, coughing, sputum production)
   - The patient has an increase in FEV1 of at least 5% from pretreatment baseline

   If yes, **approve all formulations of the 100mg strength for 12 months by GPID or GPI-14 with a quantity limit of #1 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

7. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) (ICD-10 Group D72.11) and meet **ALL** of the following criteria?
   - The patient has a reduction in frequency/severity of HES flares
   - The patient has improved symptoms or reduced oral steroid (e.g., prednisone) requirements
   - Nucala will NOT be used concurrently with another systemic biologic (e.g., Fasenra [benralizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HES

   If yes, **approve all formulations of the 100mg strength for 12 months by GPID or GPI-14 with a quantity limit of #3 per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
      2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
      3. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (a type of immune system disorder with inflammation of blood vessels)
      4. Chronic obstructive pulmonary disease (COPD: a type of long-term lung condition)
      5. Hypereosinophilic syndrome (HES: a type of blood disorder)

   (Renewal denial text continued on next page)

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

B. If you have severe asthma with an eosinophilic phenotype, renewal also requires:
1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma (a type of lung condition with inflammation)
3. You have shown a clinical response as evidenced by ONE of the following:
   a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Nucala)
   b. You have decreased your use of rescue medications (such as albuterol)
   c. You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Nucala)
   d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. If you have chronic rhinosinusitis with nasal polyps, renewal also requires:
1. You have shown a clinical benefit compared to baseline (before starting Nucala) (such as improvements in nasal congestion, sense of smell, size of polyps)
2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps (inflammation of nasal and sinus passages with small growths in the nose)

D. If you have eosinophilic granulomatosis with polyangiitis, renewal also requires:
1. You have shown a reduction in eosinophilic granulomatosis with polyangiitis (EGPA) symptoms compared to baseline (before starting Nucala), OR you have been able to decrease or eliminate (stop) corticosteroid use
2. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic granulomatosis with polyangiitis (a type of immune system disorder with inflammation of blood vessels)

(Renewal denial text continued on next page)

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

E. If you have chronic obstructive pulmonary disease, renewal also requires:
1. You have an eosinophilic phenotype of chronic obstructive pulmonary disease (COPD: a type of inflammatory long-term lung condition)
2. Nucala will be used in combination with a long-acting muscarinic antagonist (LAMA)/long-acting beta-2-agonist (LABA)/inhaled corticosteroid (ICS) (such as Trelegy Ellipta, Breztri Aerosphere)
3. You will NOT use Nucala concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Daliresp (roflumilast)]) for the treatment of eosinophilic phenotype chronic obstructive pulmonary disease (a type of long-term lung condition)
4. You have shown a clinical response as evidenced by ONE of the following:
   a. You have a reduction (decrease) in COPD exacerbations (worsening of symptoms) from baseline (before starting Nucala)
   b. You have a reduction in severity or frequency of COPD-related symptoms (such as wheezing, shortness of breath, coughing, sputum [mucus] production)
   c. You have had an increase in FEV1 (a type of lung test) by at least 5% from pretreatment baseline

F. If you have hypereosinophilic syndrome, renewal also requires:
1. You have a reduction in frequency/severity of hypereosinophilic syndrome (HES: a type of blood disorder) flares
2. You have improved symptoms or reduced oral steroid (such as prednisone) requirements
3. You will NOT use Nucala concurrently (at the same time) with another systemic biologic (such as Fasenra [benralizumab]) or targeted small molecules (such as JAK inhibitor, PDE-4 inhibitor) for the treatment of hypereosinophilic syndrome (a type of blood disorder)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nucala.

REFERENCES
Nucala [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline LLC.; August 2025.

Created: 11/15
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METFORMIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METFORMIN HCL	RIOMET, METFORMIN HCL		20808	GPI-14 (27250050002020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E11, E13) and meet **ALL** of the following criteria?
   - The patient is 10 years of age or older
   - The patient has a contraindication to or is unable to swallow metformin tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METFORMIN (Riomet)** requires the following rule(s) be met for approval:
   A. You have type 2 diabetes mellitus (a disorder with high blood sugar)
   B. You are 10 years of age or older
   C. You have a contraindication to (harmful for you to use) or are unable to swallow metformin tablets

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Riomet.

REFERENCES

Riomet [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; November 2018.

Created: 05/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOCARBAMOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHOCARBAMOL	ATMEKSI		58157	GPI-14 (75100070001820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of an acute, painful musculoskeletal condition **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow generic methocarbamol tablets

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHOCARBAMOL (Atmeksi)** requires the following rule(s) be met for approval:
   A. You have an acute, painful musculoskeletal condition (sudden and severe pain relating to muscles and bones)
   B. You have a contraindication to (harmful for you to use) or are unable to swallow generic methocarbamol tablets

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Atmeksi.

REFERENCES

Atmeksi [Prescribing Information]. Watkinsville, GA: Rosemont Pharmaceuticals, Inc; July 2025.

Created: 04/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOTREXATE - JYLAMVO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHOTREXATE	JYLAMVO	03906		GPI-10 (2130005000)	BRAND = JYLAMVO

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) and meet **ALL** of the following criteria?
   - Jylamvo will be used as part of a combination chemotherapy maintenance regimen
   - The patient has a contraindication to or is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient have a diagnosis of mycosis fungoides (cutaneous T-cell lymphoma) (ICD-10 Group C84.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #3.

3. Does the patient have a diagnosis of relapsed or refractory non-Hodgkin lymphoma (ICD-10 Group C85) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Jylamvo will be used as part of a metronomic combination chemotherapy regimen
   - The patient has a contraindication to or is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of rheumatoid arthritis (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per 28 days.**
   If no, continue to #5.

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METHOTREXATE - JYLAMVO

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 Group M08) **AND** meet the following criterion?
   - The patient has a contraindication to or is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #6.

6. Does the patient have a diagnosis of severe psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #60mL per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHOTREXATE - JYLAMVO** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Acute lymphoblastic leukemia (ALL: a type of blood cancer)
      2. Mycosis fungoides (cutaneous T-cell lymphoma) (a type of blood cancer affecting the skin)
      3. Relapsed or refractory non-Hodgkin lymphoma (a type of blood cancer that has returned or did not respond to treatment)
      4. Rheumatoid arthritis (a type of joint condition)
      5. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
      6. Severe psoriasis (a type of skin condition)

   B. If you have acute lymphoblastic leukemia, approval also requires:
      1. Jylamvo will be used as part of a combination chemotherapy maintenance regimen (a type of therapy to treat cancer)
      2. You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

   C. If you have mycosis fungoides (cutaneous T-cell lymphoma), approval also requires:
      1. You are 18 years of age or older
      2. You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

   (Denial text continued on next page)

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METHOTREXATE - JYLAMVO

GUIDELINES FOR USE (CONTINUED)

D. If you have relapsed or refractory non-Hodgkin lymphoma, approval also requires:
1. You are 18 years of age or older
2. Jylamvo will be used as part of a metronomic combination chemotherapy regimen (a type of therapy to treat cancer where lower doses are given over a long period to reduce side effects)
3. You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

E. If you have rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

F. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

G. If you have severe psoriasis, approval also requires:
1. You are 18 years of age or older
2. You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Jylamvo.

REFERENCES
Jylamvo [Prescribing Information]. Cambridge, MA: Shorla Oncology Inc.; March 2025.

Created: 11/23
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOTREXATE - XATMEP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHOTREXATE	XATMEP		43319	GPI-14 (21300050002080)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0) and meet **ALL** of the following criteria?
   - Xatmep will be used as part of a multi-phase combination chemotherapy maintenance regimen
   - The patient has a contraindication to or is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, continue to #2.

2. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3; Group M08) and meet **ALL** of the following criteria?
   - The patient had an insufficient response to or is intolerant of first-line therapy (including non-steroidal anti-inflammatory agents [NSAIDs (e.g., ibuprofen)])
   - The patient has a contraindication to or is unable to swallow generic methotrexate tablets

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHOTREXATE - XATMEP** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Acute lymphoblastic leukemia (ALL: a type of blood cancer)
      2. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   B. If you have acute lymphoblastic leukemia, approval also requires:
      1. Xatmep will be used as part of a combination chemotherapy maintenance regimen (a type of therapy to treat cancer)
      2. You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets
   C. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
      1. You had an insufficient response to (medication did not work) or are intolerant of (side effects) first-line therapy, including non-steroidal anti-inflammatory drugs (NSAIDs such as ibuprofen)
      2. You have a contraindication to (harmful for you to use) or are unable to swallow generic methotrexate tablets

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METHOTREXATE - XATMEP

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xatmep.

REFERENCES

Xatmep [Prescribing Information]. Wilmington, MA: Azurity Pharmaceuticals, Inc.; September 2020.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHOXY PEG-EPOETIN BETA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHOXY PEG-EPOETIN BETA	MIRCERA	35005		GPI-10 (8240104010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   - Mircera will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Epogen [epoetin alfa], Procrit [epoetin alfa]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
   - The patient had a trial of the preferred agent: Retacrit (epoetin alfa-epbx)
   - The patient's hemoglobin level is less than 10g/dL

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, continue to #3.

3. Is the patient between 3 months and 17 years of age **AND** meets the following criterion?
   - The patient is converting from another erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Aranesp [darbepoetin alfa]) after the hemoglobin level has been stabilized with that ESA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHOXY PEG-EPOETIN BETA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for approval:

A. You have anemia (a type of blood condition) associated with chronic (long-term) kidney disease (CKD)
B. You are 3 months of age or older
C. You will NOT use Micera concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Epogen [epoetin alfa], Procrit [epoetin alfa]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])
D. If you are 18 years of age or older, approval also requires:
    1. You have tried the preferred medication: Retacrit (epoetin alfa-epbx)
    2. Your hemoglobin level (type of blood test) is less than 10g/dL
E. If you are between 3 months and 17 years of age, approval also requires:
    1. You are changing from another erythropoiesis-stimulating agent (ESA, such as Epogen [epoetin alfa], Aranesp [darbepoetin alfa]) after your hemoglobin level (type of blood test) has been stabilized with that ESA

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHOXY PEG-EPOETIN BETA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) (ICD-10 D63.1) **AND** meet the following criterion?
   - Mircera will NOT be used concurrently with another erythropoiesis-stimulating agent (ESA) (e.g., Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Epogen [epoetin alfa], Procrit [epoetin alfa]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (e.g., Jesduvroq [daprodustat], Vafseo [vadadustat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 18 years of age or older and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 10g/dL if not on dialysis
   - The patient's hemoglobin level is less than 11g/dL if on dialysis
   - The patient's hemoglobin level has reached 10g/dL (if not on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions
   - The patient's hemoglobin level has reached 11g/dL (if on dialysis) and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, continue to #3.

3. Is the patient between 3 months and 17 years of age and meets **ONE** of the following criteria?
   - The patient's hemoglobin level is less than 12g/dL
   - The patient's hemoglobin level has reached 12g/dL and the dose is being or has been reduced/interrupted to decrease the need for blood transfusions

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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METHOXY PEG-EPOETIN BETA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHOXY PEG-EPOETIN BETA (Mircera)** requires the following rule(s) be met for renewal:

A. You have anemia (a type of blood condition) associated with chronic (long-term) kidney disease (CKD)
B. You are 3 months of age or older
C. You will NOT use Micera concurrently (at the same time) with another erythropoiesis-stimulating agent (ESA) (such as Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Epogen [epoetin alfa], Procrit [epoetin alfa]) OR hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) (such as Jesduvroq [daprodustat], Vafseo [vadadustat])
D. If you are 18 years of age or older, renewal also requires ONE of the following:
    1. Your hemoglobin level (type of blood test) is less than 10g/dL if you are not on dialysis (process of removing excess water, toxins from the blood)
    2. Your hemoglobin level (type of blood test) is less than 11g/dL if you are on dialysis (process of removing excess water, toxins from the blood)
    3. Your hemoglobin level (type of blood test) has reached 10g/dL (if you are not on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
    4. Your hemoglobin level (type of blood test) has reached 11g/dL (if you are on dialysis [process of removing excess water, toxins from the blood]) and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)
E. If you are between 3 months and 17 years of age, renewal also requires ONE of the following:
    1. Your hemoglobin level (type of blood test) is less than 12g/dL
    2. Your hemoglobin level (type of blood test) has reached 12g/dL and your dose is being or has been reduced or interrupted to decrease the need for blood transfusions (adding blood to your body)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHOXY PEG-EPOETIN BETA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mircera.

REFERENCES

Mircera [Prescribing Information]. St. Gallen, Switzerland: Vifor Inc.; June 2024.

Created: 02/11
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHYLNALTREXONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHYLNALTREXONE BROMIDE	RELISTOR	35611		GPI-10 (5258005010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of opioid-induced constipation (OIC) (ICD-10 K59.03) with chronic non-cancer pain (ICD-10 G89.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has chronic non-cancer pain, including chronic pain related to prior cancer or its treatment
   - The patient does NOT require frequent opioid dosage escalation
   - The patient has been taking opioids for at least four weeks
   - The patient had a trial of or contraindication to the preferred agents: Symproic (naldemedine) and Movantik (naloxegol)

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **12 mg: #0.6 mL per day.**
   - **150 mg: #3 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of opioid-induced constipation (OIC) (ICD-10 K59.03) with advanced illness or pain caused by active cancer (ICD-10 G89.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The request is for Relistor injection
   - The patient requires opioid dosage escalation for palliative care

   If yes, **approve all strengths and formulations for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **12 mg: #0.6 mL per day.**
   - **8 mg: #0.4 mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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METHYLNALTREXONE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METHYLNALTREXONE (Relistor)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Opioid-induced constipation (a type of bowel disorder caused by drugs used to treat pain) with chronic (long-term) non-cancer pain
   2. Opioid-induced constipation with advanced illness or pain caused by active cancer

B. If you have opioid-induced constipation with chronic non-cancer pain, approval also requires:
   1. You are 18 years of age or older
   2. You have chronic non-cancer pain, including chronic pain related to prior cancer or its treatment
   3. You do NOT require frequent opioid dosage escalation (increase)
   4. You have been taking opioids for at least four weeks
   5. You have tried or have a contraindication to (harmful for you to use) the preferred medications: Symproic (naldemedine) AND Movantik (naloxegol)

C. If you have opioid-induced constipation with advanced illness or pain caused by active cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your request is for Relistor injection
   3. You require opioid dosage escalation (increase) for palliative care (treatment for comfort from symptoms)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Relistor.

REFERENCES

Relistor [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals; May 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METHYLTESTOSTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METHYLTESTOSTERONE	TESTRED, ANDROID, METHITEST, METHYLTESTOS-TERONE		10380 10411	GPI-10 (2310002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1)?

   If yes, continue to #2.
   If no, continue to #6.

2. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   - The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 40 years of age or older?

   If yes, continue to #4.
   If no, continue to #5.

4. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

5. Has the patient had a trial of or contraindication to **TWO** preferred agents: intramuscular testosterone cypionate and intramuscular testosterone enanthate?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0), not secondary to a pathological disorder, who meets the following criterion?
   - The patient had a trial of or contraindication to intramuscular testosterone enanthate

   If yes, **approve the requested agent for 6 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, continue to #7.

7. Is the request for a female patient with a diagnosis of metastatic breast cancer (ICD-10 Group C50) who meets the following criterion?
   - The patient had a trial of or contraindication to intramuscular testosterone enanthate

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient is postmenopausal
   - The patient is premenopausal who benefited from an oophorectomy AND is considered to have a hormone-responsive tumor

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #20 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

9. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 (PAC Note: Please override the quantity limit coded on the formulary).**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Delayed puberty not due to a pathological disorder (not due to a disease) in a male
      3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
      4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

   B. If you are a male with primary or secondary hypogonadism, approval also requires:
      1. You meet ONE of the following showing you have low testosterone levels:
         a. You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         b. You have a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
      2. You have tried or have a contraindication to (harmful for you to use) TWO preferred medications: intramuscular [injected into the muscle] testosterone cypionate, intramuscular testosterone enanthate
      3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
         a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
         b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   (Initial denial text continues on next page)

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METHYLTESTOSTERONE

INITIAL CRITERIA (CONTINUED)

C. If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:
1. You have tried or have a contraindication to (harmful for you to use) intramuscular (injected into the muscle) testosterone enanthate

D. If you are a female with metastatic breast cancer, approval also requires:
1. You have tried or have a contraindication to (harmful for you to use) intramuscular (injected into the muscle) testosterone enanthate
2. You meet ONE of the following:
   a. You are postmenopausal (after menopause)
   b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

E. If you have gender dysphoria, approval also requires:
1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METHYLTESTOSTERONE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

3. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0), not secondary to a pathological disorder, who meets the following criterion?
   - The patient has not received more than two 6-month courses of testosterone replacement therapy

   If yes, **approve the requested agent for 6 months by GPID or GPI-14 with a quantity limit of #5 per day.**

   If no, continue to #5.

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METHYLTESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

5. Is the request for a female patient with a diagnosis of metastatic breast cancer (ICD-10 Group C50) who meets **ONE** of the following criteria?
   - The patient is postmenopausal
   - The patient is premenopausal who benefited from an oophorectomy AND is considered to have a hormone-responsive tumor

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 with a quantity limit of #20 per day.**

   If no, continue to #6.

6. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 (PAC Note: Please override the quantity limit coded on the formulary).**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METHYLTESTOSTERONE (Testred, Android, Methitest)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Delayed puberty not due to a pathological disorder (not due to a disease) in a male
      3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
      4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

   (Renewal denial text continues on next page)

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METHYLTESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

B. If you are a male with primary or secondary hypogonadism, renewal also requires:
1. You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
2. You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
   a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
   b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

C. If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:
1. You have NOT received more than two 6-month courses of testosterone replacement therapy

D. If you are a female with metastatic breast cancer, renewal also requires ONE of the following:
1. You are postmenopausal (after menopause)
2. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive

E. If you have gender dysphoria, renewal also requires:
1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Testred, Android, and Methitest.

REFERENCES

Android [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; April 2015.
Methitest [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2025.
Testred [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; April 2015.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METOCLOPRAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METOCLOPRAMIDE HCL	GIMOTI		48272	GPI-14 (52300020102080)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute and recurrent diabetic gastroparesis (ICD-10 K31.84) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the clinical standard of care agent: metoclopramide ODT

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #9.8mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METOCLOPRAMIDE (Gimoti)** requires the following rule(s) be met for approval:
   A. You have acute (short duration) and recurrent (occurring repeatedly) diabetic gastroparesis (a disorder from high blood sugar that causes delayed emptying of food from the stomach)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: metoclopramide ODT (orally disintegrating tablet)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gimoti.

REFERENCES

Gimoti [Prescribing Information]. Solana Beach, CA: Evoke Pharma, Inc.; January 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METOPROLOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METOPROLOL TARTRATE	LOPRESSOR		56737	GPI-14 (33200030102020)	

GUIDELINES FOR USE

1. Does the patient have a contraindication to or is unable to swallow metoprolol tartrate tablets?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #45mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METOPROLOL (Lopressor)** requires the following rule(s) be met for approval:
   A. You have a contraindication to (harmful for you to use) or are unable to swallow metoprolol tartrate tablets

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lopressor.

REFERENCES

Lopressor [Prescribing Information]. Parsippany, NJ: Validus Pharmaceuticals LLC; April 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METRELEPTIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METRELEPTIN	MYALEPT	41078		GPI-10 (3090605000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of congenital or acquired generalized lipodystrophy (ICD-10 E88.1) and meet **ALL** of the following criteria?
   - Myalept will be used as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has diabetes mellitus, insulin resistance, OR a fasting hypertriglyceridemia of greater than 200mg/dL

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METRELEPTIN (Myalept)** requires the following rule(s) be met for approval:
   A. You have congenital or acquired generalized lipodystrophy (abnormal distribution of fat in the body)
   B. Myalept will be used as an adjunct (add-on) to diet as replacement therapy to treat the complications of leptin deficiency (low level of a type of hormone)
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. You have diabetes mellitus (a disorder with high blood sugar), insulin resistance (a condition where cells in the body do not respond to a type of hormone), OR a fasting hypertriglyceridemia (high levels of fat in the blood) of greater than 200mg/dL

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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METRELEPTIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of congenital or acquired generalized lipodystrophy (ICD-10 E88.1) **AND** meet the following criterion?
   - The patient has shown clinical benefit with the use of Myalept (e.g., reduction in glucose levels, reduction of insulin resistance, or reduction of triglycerides)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METRELEPTIN (Myalept)** requires the following rule(s) be met for renewal:
   A. You have congenital or acquired generalized lipodystrophy (abnormal distribution of fat in the body)
   B. You have shown clinical benefit (improvement) with the use of Myalept (such as a reduction in glucose levels [lower level of blood sugar], reduction of insulin resistance [cells in the body are more responsive to a type of hormone], or reduction of triglycerides [lower level of fat in the blood])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myalept.

REFERENCES

Myalept [Prescribing Information]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; February 2022.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METRONIDAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METRONIDAZOLE	LIKMEZ	04157		GPI-10 (1600003500)	BRAND = LIKMEZ

GUIDELINES FOR USE

1. Is the request for the treatment of trichomoniasis (ICD-10 Group A59) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow metronidazole tablets

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #400mL per 10 days for 1 fill.**

   If no, continue to #2.

2. Is the request for the treatment of acute intestinal amebiasis (amoebic dysentery) (ICD-10 A06.0) or amebic liver abscess (ICD-10 A06.4), **AND** the patient meets the following criterion?
   - The patient has a contraindication to or is unable to swallow metronidazole tablets

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #400mL per 10 days for 1 fill.**

   If no, continue to #3.

3. Is the request for the treatment of serious infections caused by susceptible anaerobic bacteria (e.g., *Bacteroides* species, *Clostridium* species, *Peptococcus* species) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a contraindication to or is unable to swallow metronidazole tablets

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit of #400mL per 10 days for 1 fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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METRONIDAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METRONIDAZOLE (Likmez)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Trichomoniasis (a type of infection caused by a parasite)
   2. Acute intestinal amebiasis (amoebic dysentery: a type of infection of the intestines) OR amebic liver abscess (a collection of pus in the liver caused by a parasite)
   3. Serious infections caused by susceptible anaerobic bacteria, such as *Bacteroides* species, *Clostridium* species, *Peptococcus* species (infections caused by types of bacteria that can be treated with metronidazole)

B. You have a contraindication to (harmful for you to use) or are unable to swallow metronidazole tablets

C. For the treatment of trichomoniasis or serious infections caused by susceptible anaerobic bacteria, approval also requires:
   1. You are 18 years of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Likmez.

REFERENCES

Likmez [Prescribing Information]. Hauppauge, NY: Saptalis Pharmaceuticals LLC; July 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METYROSINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METYROSINE	DEMSER, METYROSINE	00138		GPI-10 (3630002500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pheochromocytoma (ICD-10 Groups D35.0, C74.1) and the requested medication will be used for **ONE** of the following?
   - Preoperative preparation for surgery
   - Management of malignant pheochromocytoma when surgery is contraindicated
   - Chronic treatment of patients with malignant pheochromocytoma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following?
   - The patient has a non-metastatic pheochromocytoma
   - Therapy is prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist-oncologist

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient awaiting surgery?

   If yes, continue to #4.
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #16 per day.**

4. Will the requested medication be used in combination with an alpha-adrenergic receptor blocker (e.g., doxazosin, terazosin, prazosin, phenoxybenzamine)?

   If yes, **approve for 30 days by HICL or GPI-10 with a quantity limit of #224 per 14 days for one fill.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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METYROSINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **METYROSINE (Demser)** requires the following rule(s) be met for approval:

A. You have pheochromocytoma (a type of rare tumor)
B. You will be using the requested medication for ONE of the following:
   1. Preoperative preparation for surgery
   2. Management of malignant (cancerous) pheochromocytoma when surgery is contraindicated (harmful for you to have)
   3. Chronic (long term) treatment of malignant pheochromocytoma
C. You have a non-metastatic pheochromocytoma (tumor has not spread to other parts of the body)
D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist-oncologist (a type of cancer doctor)
E. If you are awaiting surgery, approval also requires:
   1. The requested medication will be in combination with an alpha-adrenergic receptor blocker (such as doxazosin, terazosin, prazosin, phenoxybenzamine)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

METYROSINE

RENEWAL CRITERIA

NOTE: For the request of pre-operative preparation for surgery, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of pheochromocytoma (ICD-10 Groups D35.0, C74.1) and the requested medication will be used for **ONE** of the following?
   - Management of malignant pheochromocytoma when surgery is contraindicated
   - Chronic treatment of patients with malignant pheochromocytoma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient stable or has shown clinical improvement while on therapy?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #16 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **METYROSINE (Demser)** requires the following rule(s) be met for renewal:
   A. You have pheochromocytoma (a type of rare tumor)
   B. You will be using the requested medication for ONE of the following:
      1. Management of malignant (cancerous) pheochromocytoma when surgery is contraindicated (harmful for you to have)
      2. Chronic (long term) treatment of malignant pheochromocytoma
   C. You are stable or have shown clinical improvement while on therapy (treatment)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Demser.

REFERENCES

Demser [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; July 2021.

Created: 04/25
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIDAZOLAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIDAZOLAM	NAYZILAM	10329		GPI-10 (7210006000)	BRAND = NAYZILAM

GUIDELINES FOR USE

1. Does the patient have a diagnosis of epilepsy (ICD-10 Group G40) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Nayzilam will be used for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (seizure clusters, acute repetitive seizures) that are distinct from the patient's usual seizure pattern

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIDAZOLAM (Nayzilam)** requires the following rule(s) be met for approval:
   A. You have epilepsy (a type of brain disorder)
   B. You are 12 years of age or older
   C. Nayzilam will be used for the acute (short-term) treatment of intermittent, stereotypic episodes of frequent seizure activity (a condition of increased seizure activity) (seizure clusters, acute repetitive seizures) that are different from your usual seizure pattern

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nayzilam.

REFERENCES
Nayzilam [Prescribing Information]. Smyrna, GA: UCB, Inc.; January 2023.

Created: 05/26
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIDOSTAURIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIDOSTAURIN	RYDAPT	44227		GPI-10 (2153303000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is newly diagnosed (e.g., starting or previously started Rydapt treatment at the time of diagnosis)
   - The patient's cancer is FLT3 mutation-positive as detected by an FDA-approved test
   - Rydapt will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #56 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM) (ICD-10 C96.21), systemic mastocytosis with an associated hematological neoplasm (SM-AHN) (ICD-10 D47.02), or mast cell leukemia (MCL) (ICD-10 Group C94.3) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #224 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIDOSTAURIN (Rydapt)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)
      2. Aggressive systemic mastocytosis (ASM: a type of blood disorder)
      3. Systemic mastocytosis with an associated hematological neoplasm (SM-AHN: a type of blood cancer)
      4. Mast cell leukemia (MCL: a type of blood cancer)

   (Denial text continued on next page)

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MIDOSTAURIN

GUIDELINES FOR USE (CONTINUED)

B. If you have acute myeloid leukemia, approval also requires:
1. You are 18 years of age or older
2. You are newly diagnosed (such as you are starting or previously started Rydapt treatment at the time your condition was identified)
3. Your cancer is FLT3 mutation-positive (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
4. Rydapt will be used in combination with standard cytarabine and daunorubicin induction (initial treatment) OR with cytarabine consolidation chemotherapy (treatment following initial therapy)

C. If you have aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm, or mast cell leukemia, approval also requires:
1. You are 18 years of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or drug monograph for Rydapt.

REFERENCES

Rydapt [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2023.

Created: 08/17
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIFEPRISTONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIFEPRISTONE	KORLYM, MIFEPRISTONE		31485	GPI-10 (2730405000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of endogenous Cushing's syndrome (CS) (ICD-10 Group E24 except ICD-10 E24.2 and E24.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's hypercortisolism is NOT a result of chronic glucocorticoids (e.g., prednisone)
   - The patient also has a diagnosis of type 2 diabetes mellitus (ICD-10 Groups E08, E09, E11, E13) OR glucose intolerance
   - The patient has failed surgical treatment for Cushing's syndrome OR is not a candidate for surgery
   - The patient had a trial of or contraindication to the clinical standard of care agent: ketoconazole
   - The requested medication will NOT be used concurrently with other agents to lower cortisol (e.g., Recorlev [levoketoconazole], Isturisa [osilodrostat]) for the treatment of Cushing’s disease/syndrome

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the diagnosis of endogenous Cushing’s syndrome been confirmed by **ONE** of the following tests?
   - 24-hour urine free cortisol (at least 2 tests to confirm)
   - Overnight 1mg dexamethasone test
   - Late-night salivary cortisol (at least 2 tests to confirm)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MIFEPRISTONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for approval:

A. You have endogenous Cushing's syndrome (CS: a type of hormone disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your hypercortisolism (high levels of cortisol) is NOT due to chronic glucocorticoids (long-term use of a class of medications that consists of steroids, such as prednisone)
E. You also have type 2 diabetes mellitus (a disorder with high blood sugar) OR glucose intolerance (a condition that results in high blood sugar)
F. You have failed surgical treatment (surgery did not work) for Cushing's syndrome (a type of hormone disorder) OR you are NOT a candidate for surgery
G. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ketoconazole
H. You will NOT use the requested medication concurrently (at the same time) with other medications to lower cortisol (such as Recorlev [levoketoconazole], Isturisa [osilodrostat]) for the treatment of Cushing’s disease/syndrome (a type of hormone disorder)
I. Your diagnosis is confirmed by ONE of the following:
    1. A 24-hour urine free cortisol (a type of test that measures the amount of cortisol in the urine) (at least 2 tests to confirm)
    2. An overnight 1mg dexamethasone test (a type of diagnostic test)
    3. A late-night salivary cortisol (a type of test that measures the amount of cortisol in the saliva at night) (at least 2 tests to confirm)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIFEPRISTONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of endogenous Cushing's syndrome (CS) (ICD-10 Group E24 except ICD-10 E24.2 and E24.4) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of glucose tolerance or stable glucose tolerance (e.g., reduced A1C, improved fasting glucose)
   - The patient continues to have tolerability to Korlym (mifepristone)
   - The patient continues to NOT be a candidate for surgical treatment for Cushing's syndrome OR has failed surgery
   - The requested medication will NOT be used concurrently with other agents to lower cortisol (e.g., Recorlev [levoketoconazole], Isturisa [osilodrostat]) for the treatment of Cushing's disease/syndrome

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for renewal:
   A. You have endogenous Cushing's syndrome (CS: a type of hormone disorder)
   B. You continue to have improvement of glucose tolerance or stable glucose tolerance (such as reduced hemoglobin A1C level [a type of lab test], improved fasting glucose)
   C. You continue to tolerate Korlym (mifepristone)
   D. You are NOT a candidate for surgery OR you have failed surgery (surgery did not work) for Cushing's syndrome (a type of hormone disorder)
   E. You will NOT use the requested medication concurrently (at the same time) with other medications to lower cortisol (such as Recorlev [levoketoconazole], Isturisa [osilodrostat]) for the treatment of Cushing's disease/syndrome (a type of hormone disorder)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Korlym.

REFERENCE

Korlym [Prescribing Information]. Redwood City, CA: Corcept Therapeutics Incorporated; September 2024.

Created: 04/12
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGALASTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGALASTAT HCL	GALAFOLD	44433		GPI-10 (3090365010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
   - The patient has an amenable galactosidase alpha (GLA) gene variant based on in vitro assay data as interpreted by a clinical genetics professional as pathogenic or likely pathogenic (i.e., patient does NOT have a benign amenable GLA variant)
   - Galafold will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
   - The patient is symptomatic OR has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a female **AND** the patient meets the following criterion?
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, continue to #3.

3. Is the request for a male and the patient meets **ONE** of the following criteria?
   - The patient has an alpha galactosidase A (a-Gal-A) deficiency as indicated by an enzyme assay
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MIGALASTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for approval:

A. You have Fabry disease (a rare genetic disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor), cardiologist (a type of heart doctor), or a doctor specializing in genetics or inherited metabolic disorders
D. You have an amenable (responsive) galactosidase alpha (GLA) gene variant (abnormal change in a type of gene) based on in vitro assay data (data collected from lab test tubes or cultures) that is interpreted by a clinical genetics professional as the cause of disease (pathogenic or likely pathogenic)
E. You will NOT use Galafold concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
F. You are symptomatic OR have evidence of injury from GL-3 (globotriaosylceramide: a type of fat) to the kidney, heart, or central nervous system recognized by laboratory, histological (viewed by microscope), or imaging findings. Evidence of injury may include decreased GFR (glomerular filtration rate: a tool for evaluating kidney function) for age, persistent albuminuria (protein in urine), cerebral white matter lesions on brain MRI (magnetic resonance imaging: type of imaging lab), cardiac fibrosis (abnormal thickening of heart valves) on contrast cardiac MRI
G. If you are a female, approval also requires:
    1. You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing
H. If you are a male, approval also requires ONE of the following:
    1. You do NOT have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
    2. You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIGALASTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) **AND** meet the following criterion?
   - Galafold will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy?
   - Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
   - Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
   - Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #14 per 28 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for renewal:
   A. You have Fabry disease (a rare genetic disease)
   B. You will NOT use Galafold concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Elfabrio [pegunigalsidase alfa-iwxj])
   C. You have demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy:
      1. Symptoms (such as pain, hypohidrosis [less sweating]/anhidrosis [no sweating], exercise intolerance, gastrointestinal [GI] symptoms, angiokeratomas [dark red-blue raised spots on the skin], abnormal cornea [a part of the eye], tinnitus [ringing in the ears]/hearing loss)
      2. Imaging (such as brain/cardiac MRI [magnetic resonance imaging: type of imaging lab], DEXA [a type of bone scan], renal [kidney] ultrasound)
      3. Laboratory or histological (viewed by microscope) testing (such as GL-3 [globotriaosylceramide: a type of fat] in plasma/urine, renal biopsy [removal of cells or tissue from the body for examination])

   (Renewal denial text continued on next page)

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MIGALASTAT

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Galafold.

REFERENCES

Galafold [Prescribing Information]. Philadelphia, PA: Amicus Therapeutics; October 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/18
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGLUSTAT-OPFOLDA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGLUSTAT	OPFOLDA	25098		GPI-10 (3090776000)	BRAND = OPFOLDA

GUIDELINES FOR USE

1. Does the patient have a diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (ICD-10 E74.02) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient weighs at least 40 kgs (88 lbs.)
   - The patient is not improving on their current enzyme replacement therapy (ERT) (e.g., Lumizyme [alglucosidase alfa])
   - Opfolda will be used in combination with Pombiliti (cipaglucosidase alfa-atga)

   If yes, **approve for lifetime by GPID or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIGLUSTAT-OPFOLDA** requires the following rule(s) be met for approval:
   A. You have late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) (a type of genetic disorder)
   B. You are 18 years of age or older
   C. You weigh at least 40 kilograms (88 pounds)
   D. You are NOT improving on your current enzyme replacement therapy (ERT) (such as Lumizyme [alglucosidase alfa])
   E. Opfolda will be used in combination with Pombiliti (cipaglucosidase alfa-atga)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGLUSTAT-OPFOLDA

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Opfolda.

REFERENCES
Opfolda [Prescribing Information]. Philadelphia, PA: Amicus Therapeutics US, LLC; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIGLUSTAT-ZAVESCA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIGLUSTAT	ZAVESCA, YARGESA, MIGLUSTAT		19453	GPI-10 (8270007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mild to moderate type 1 Gaucher disease (ICD-10 E75.22) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as monotherapy
   - Enzyme replacement therapy is not a therapeutic option for this patient (e.g., due to allergy, hypersensitivity, poor venous access)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #90 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Niemann-Pick disease type C (NPC) (ICD-10 E75.242) **AND** meet the following criterion?
   - The requested medication will be used in combination with Miplyffa (arimoclomol)

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIGLUSTAT-ZAVESCA (Yargesa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Mild to moderate type 1 Gaucher disease (a type of genetic condition)
   2. Niemann-Pick disease type C (NPC: a type of genetic condition)

B. If you have mild to moderate type 1 Gaucher disease, approval also requires:
   1. You are 18 years of age or older
   2. The requested medication will be used as monotherapy (one drug treatment)
   3. Enzyme replacement therapy (a type of treatment) is not a therapeutic option for you (due to reasons such as allergy, hypersensitivity [allergic reaction], poor access to veins)

C. If you have Niemann-Pick disease type C, approval also requires:
   1. The requested medication will be used in combination with Miplyffa (arimoclomol)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIGLUSTAT-ZAVESCA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zavesca and Yargesa.

REFERENCES

Zavesca [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; August 2022.
Yargesa [Prescribing Information]. Parsippany, NJ: Edenbridge Pharmaceuticals, LLC; October 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/14/24
Created: 05/05
Client Approval: 10/24
P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MILTEFOSINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MILTEFOSINE	IMPAVIDO	16200		GPI-10 (1600003600)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Visceral leishmaniasis (ICD-10 B55.0) caused by *Leishmania donovani*
   - Cutaneous leishmaniasis (ICD-10 B55.1) caused by *Leishmania braziliensis, Leishmania guyanensis*, or *Leishmania panamensis*
   - Mucosal leishmaniasis (ICD-10 B55.2) caused by *Leishmania braziliensis*

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the Leishmaniasis species been identified by **ONE** of the following CDC recommended tests?
   - Stained slides (using tissue from biopsy specimens, impression smears, or dermal scrapings)
   - Culture medium
   - Polymerase chain reaction (PCR)
   - Serologic testing (e.g., rK39 Rapid Test)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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MILTEFOSINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline for **MILTEFOSINE (Impavido)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Visceral leishmaniasis caused by *Leishmania donovani* (a type of parasitic disease that affects the organs)
   2. Cutaneous leishmaniasis caused by *Leishmania braziliensis, Leishmania guyanensis, or Leishmania panamensis* (a type of parasitic disease that affects the skin)
   3. Mucosal leishmaniasis caused by *Leishmania braziliensis* (a type of parasitic disease that affects the inside of the mouth, throat, and nose)

B. The *Leishmaniasis* species have been identified by ONE of the following CDC (Center for Disease Control and Prevention) recommended tests:
   1. Stained slides (using tissue from biopsy specimens [removal of tissue from the body for examination], impression smears [removal of cells from the body for examination] or dermal scrapings [removal of cells from the body for examination])
   2. Culture medium (a type of lab test)
   3. Polymerase chain reaction (PCR: a type of lab test)
   4. Serologic testing (a type of blood test, such as rK39 Rapid Test)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Impavido.

REFERENCES

Impavido [Prescribing Information]. Orlando, FL: Profounda, Inc.; May 2021.

Created: 04/16
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 05/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MINOCYCLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MINOCYCLINE HCL	EMROSI		56483	GPI-14 (90060044127035)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of rosacea (ICD-10 Group L71) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has inflammatory lesions (papules and pustules) associated with rosacea
   - The patient had a trial of or contraindication to ONE generic oral minocycline or doxycycline

   If yes, **approve for 16 weeks by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MINOCYCLINE (Emrosi)** requires the following rule(s) be met for approval:
   A. You have rosacea (a type of skin condition)
   B. You are 18 years of age or older
   C. You have inflammatory lesions (papules and pustules: small bumps on the skin) associated with rosacea
   D. You have tried or have a contraindication to (harmful for you to use) ONE generic oral minocycline or doxycycline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emrosi.

REFERENCES

Emrosi [Prescribing Information]. Scottsdale, AZ: Journey Medical Corporation; November 2024.

Created: 11/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MINOCYCLINE MICROSPHERES

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MINOCYCLINE HCL MICROSPHERES	ARESTIN	25203		GPI-10 (8845205010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

1. Is this medication excluded from coverage?

   If yes, guideline does not apply.
   If no, continue to #2.

2. Does the patient have a confirmed diagnosis of periodontitis (ICD-10 Groups K05.2, K05.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oral health care professional
   - The patient does NOT have a history of minocycline or tetracycline sensitivity or allergy
   - The patient does NOT have a history of candidiasis or active oral candidiasis
   - Arestin will be administered by an oral health care professional
   - Arestin will be used as an adjunct to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
   - Arestin will NOT be used for an acutely abscessed periodontal pocket
   - Arestin will NOT be used in an immunocompromised individual, such as those immunocompromised by any of the following conditions: uncontrolled diabetes mellitus, chemotherapy, radiation therapy, HIV infection
   - Arestin will NOT be used in the regeneration of alveolar bone, either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants

   If yes, **approve for 3 months by HICL or GPI-10 for the quantity requested up to a maximum of 48 unit-dose cartridges.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MINOCYCLINE MICROSPHERES

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MINOCYCLINE MICROSPHERES (Arestin)** requires the following rule(s) be met for approval:

A. You have a confirmed diagnosis of periodontitis (inflammation and infection of the gums)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with an oral health care professional
D. You do NOT have a history of minocycline or tetracycline sensitivity or allergy
E. You do NOT have a history of candidiasis (a type of fungal infection) or active oral candidiasis
F. Arestin will be administered by an oral health care professional
G. Arestin will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
H. Arestin will NOT be used for an acutely abscessed periodontal pocket (infection with pus-filled pocket)
I. Arestin will NOT be used in an immunocompromised individual (your immune system is weakened), such as those immunocompromised by any of the following conditions:
    1. Uncontrolled diabetes mellitus (a disorder with high blood sugar)
    2. Chemotherapy (a type of drug used to treat cancer)
    3. Radiation therapy
    4. HIV (human immunodeficiency virus) infection
J. Arestin will NOT be used in the regeneration (reconstruction) of alveolar bone (part of the bone that has tooth sockets), either in preparation for or in conjunction (together) with the placement of endosseous (dental) implants or in the treatment of failing implants

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MINOCYCLINE MICROSPHERES

RENEWAL CRITERIA

1. Is this medication excluded from coverage?

   If yes, guideline does not apply.
   If no, continue to #2.

2. Does the patient have a confirmed diagnosis of periodontitis (ICD-10 Groups K05.2, K05.3) **AND** meet the following criterion?
   - Arestin will be used as an adjunct to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

   If yes, **approve for 6 months by HICL or GPI-10 for the quantity requested up to a maximum of 48 unit-dose cartridges per 3 months.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MINOCYCLINE MICROSPHERES (Arestin)** requires the following rule(s) be met for renewal:
   A. You have a confirmed diagnosis of periodontitis (inflammation and infection of the gums)
   B. Arestin will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Arestin.

REFERENCES

Arestin [Prescribing Information]. Bridgewater, NJ: OraPharma; May 2024.

Created: 08/16
Effective: 01/01/25 Client Approval: 12/24 P&T Approval: 08/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIRDAMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIRDAMETINIB	GOMEKLI	50277		GPI-10 (2153355000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurofibromatosis type 1 (NF1) (ICD-10 Q85.01) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient has symptomatic plexiform neurofibromas (PN) that cannot be completely resected

   If yes, **approve all formulations of all strengths for 12 months by GPID or GPI-14 as follows:**
   - **1mg: #8 per day.**
   - **2mg: #4 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIRDAMETINIB (Gomekli)** requires the following rule(s) be met for approval:
   A. You have neurofibromatosis type 1 (NF1: a type of skin and nervous system disorder)
   B. You are 2 years of age or older
   C. You have symptomatic plexiform neurofibromas (PN: tumors that grow along the nerves) that cannot be completely resected (cannot be completely removed by surgery)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gomekli.

REFERENCES

Gomekli [Prescribing Information]. Stamford, CT: SpringWorks Therapeutics, Inc.; February 2025.

Created: 02/25
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIRIKIZUMAB-MRKZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIRIKIZUMAB-MRKZ	OMVOH	49282		GPI-10 (5250405040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the 300mg/15mL vial for 3 months by GPID or GPI-14 with a quantity limit of #15mL per 28 days.**
   - **SECOND APPROVAL: Approve for 3 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days. (Please enter a start date of 3 DAYS BEFORE the END date of the first approval).**

   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the 300mg/15mL vial for 3 months by GPID or GPI-14 with a quantity limit of #45mL per 28 days.**
   - **SECOND APPROVAL: Approve for 3 months by HICL or GPI-10 with a quantity limit of #3mL per 28 days. (Please enter a start date of 3 DAYS BEFORE the END date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MIRIKIZUMAB-MRKZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MIRIKIZUMAB-MRKZ (Omvoh)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

B. If you have moderate to severe ulcerative colitis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

C. If you have moderate to severe Crohn's disease, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIRIKIZUMAB-MRKZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.** If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Omvoh will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIRIKIZUMAB-MRKZ (Omvoh)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
      2. Moderate to severe Crohn's disease (CD: a type of bowel disorder)

   B. If you have moderate to severe ulcerative colitis, renewal also requires:
      1. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

   C. If you have moderate to severe Crohn's disease, renewal also requires:
      1. You will NOT use Omvoh concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIRIKIZUMAB-MRKZ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Omvoh.

REFERENCES

Omvoh [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; January 2025.

Created: 11/23
Effective: 07/01/25 Client Approval: 06/25 P&T Approval: 01/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIRVETUXIMAB SORAVTANSINE-GYNX (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIRVETUXIMAB SORAVTANSINE-GYNX	ELAHERE	48453		GPI-10 (2135503020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is folate receptor-alpha (FRa) positive as determined by an FDA-approved test
   - The patient has received one to three prior systemic treatment regimen(s) (e.g., bevacizumab, Lynparza)
   - The patient will complete an ophthalmic exam, including visual acuity and slit lamp exam, prior to the initiation of Elahere and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIRVETUXIMAB SORAVTANSINE-GYNX (Elahere)** requires the following rule(s) be met for approval:
   A. You have platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers that do not respond to a type of cancer treatment)
   B. You are 18 years of age or older
   C. Your tumor is folate receptor-alpha (FRa: a type of protein) positive as determined by a Food and Drug Administration (FDA)-approved test
   D. You have received one to three prior systemic treatment regimen(s) (such as bevacizumab, Lynparza)
   E. You will complete an ophthalmic (eye) exam, including visual acuity (sharpness of vision) and slit lamp exam (a type of eye exam), before starting Elahere and at the recommended scheduled times

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MIRVETUXIMAB SORAVTANSINE-GYNX (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elahere.

REFERENCES

Elahere [Prescribing Information]. Waltham, MA: ImmunoGen, Inc., November 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 01/23
Client Approval: 02/23
P&T Approval: 01/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITAPIVAT-AQVESME

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MITAPIVAT SULFATE	AQVESME	47840		GPI-10 (8587005070)	BRAND ≠ PYRUKYND

GUIDELINES FOR USE

1. Does the patient have a diagnosis of alpha-thalassemia (ICD-10 D56.0) or beta-thalassemia (ICD-10 D56.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Aqvesme will be used for the treatment of anemia

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITAPIVAT-AQVESME** requires the following rule(s) be met for approval:
   A. You have alpha-thalassemia or beta-thalassemia (types of blood condition)
   B. You are 18 years of age or older
   C. Aqvesme will be used for the treatment of anemia (a type of blood condition)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aqvesme.

REFERENCES

Aqvesme [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals, Inc.; December 2025.

Created: 01/26
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITAPIVAT-PYRUKYND

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MITAPIVAT SULFATE	PYRUKYND	47840		GPI-10 (8587005070)	BRAND ≠ AQVESME

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemolytic anemia due to pyruvate kinase (PK) deficiency (ICD-10 D55.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient has a documented presence of at least 2 mutant alleles in the PKLR gene, of which at least 1 is a missense mutation
   - The patient has a documented hemoglobin concentration of less than or equal to 10 g/dL

   If yes, **approve all strengths for 6 months by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITAPIVAT-PYRUKYND** requires the following rule(s) be met for approval:
   A. You have hemolytic anemia (a type of blood condition) due to pyruvate kinase (PK: a type of enzyme) deficiency
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   D. You have a documented presence of at least 2 mutant alleles in the PKLR gene (two copies of a gene with abnormal changes), of which at least 1 is a missense mutation (abnormal changes in a type of gene)
   E. You have a documented hemoglobin (a type of protein in red blood cells) concentration of less than or equal to 10 g/dL

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITAPIVAT-PYRUKYND

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemolytic anemia due to pyruvate kinase (PK) deficiency (ICD-10 D55.21) **AND** meet the following criterion?
   - The patient has had clinical benefit while on Pyrukynd

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITAPIVAT-PYRUKYND** requires the following rule(s) be met for renewal:
   A. You have hemolytic anemia (a type of blood condition) due to pyruvate kinase (PK: a type of enzyme) deficiency
   B. You have had clinical benefit while on Pyrukynd

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Pyrukynd.

REFERENCES
Pyrukynd [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals, Inc.; December 2025.

Created: 05/22
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITOMYCIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MITOMYCIN	JELMYTO		47956	GPI-14 (21200050006430)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of low-grade Upper Tract Urothelial Cancer (LG-UTUC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist or urologist

   If yes, **approve for 6 weeks by GPID or GPI-14 for #4 cartons (8 vials) per 28 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITOMYCIN (Jelmyto)** requires the following rule(s) be met for approval:
   A. You have low grade Upper Tract Urothelial Cancer (LG-UTUC: type of cancer that grows in the upper part of the urinary system)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an oncologist (doctor who specializes in cancer) or urologist (doctor who specializes in the urinary tract and male reproductive organs)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITOMYCIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of low-grade upper tract urothelial cancer (LG-UTUC) and meet **ALL** of the following criteria?
   - The patient was reassessed at no sooner than 3 months after initiation of Jelmyto
   - The patient has shown complete response at time of assessment

   If yes, **approve for 11 months by GPID or GPI-14 for #1 carton (2 vials) per 30 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITOMYCIN (Jelmyto)** requires the following rule(s) be met for renewal:
   A. You have low grade Upper Tract Urothelial Cancer (LG-UTUC: type of cancer that grows in the upper part of the urinary system)
   B. You were reassessed at no sooner than 3 months after initiation of Jelmyto
   C. You showed complete response at the time of assessment

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jelmyto.

REFERENCES

Jelmyto [Prescribing Information]. Princeton, NJ: UroGen Pharma, Inc., October 2024.

Created: 08/20
Effective: 04/01/26 Client Approval: 03/26 P&T Approval: 07/20

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MITOXANTRONE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MITOXANTRONE HCL	NOVANTRONE	03932		GPI-10 (2120005500)	

GUIDELINES FOR USE

1. Is therapy prescribed by or given in consultation with an oncologist?

   If yes, **approve open ended by HICL or GPI-10.**
   If no, continue to #2.

2. Is the patient being treated for pain related to advanced hormone refractory prostate cancer or acute nonlymphocytic leukemia?

   If yes, **approve open ended by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient being treated for secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis?

   If yes, **approve for 12 months by HICL or GPI-10 (FDA dosing regimen is 12 mg/m(2) IV every 3 months).**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MITOXANTRONE** requires ONE of following rules be met for approval:
   A. The medication is prescribed by or given in consultation with an oncologist (tumor/cancer doctor)
   B. You have ONE of the following:
      1. Pain related to advanced refractory prostate cancer
      2. Acute nonlymphocytic leukemia (type of white blood cell cancer)
      3. Secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis (disease where immune system attacks nerves)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MITOXANTRONE (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Novantrone.

REFERENCES

Novantrone [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; December 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 08/08
Client Approval: 04/20

P&T Approval: 08/10

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOGAMULIZUMAB-KPKC (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOGAMULIZUMAB-KPKC	POTELIGEO	45153		GPI-10 (2135113520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Mycosis Fungoides (MF) or Sézary syndrome and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has relapsed or refractory disease
- The patient has tried and failed at least one prior systemic therapy

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MOGAMULIZUMAB-KPKC (Poteligeo)** requires the following rule(s) be met for approval:
A. You have Mycosis Fungoides or Sezary syndrome (types of blood cancers that affect the skin)
B. You are 18 years of age or older
C. You have relapsed or refractory disease (disease has returned or not responsive to therapy)
D. You have tried and failed at least one prior systemic therapy (treatment that travels in the blood throughout the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Poteligeo.

REFERENCES
Poteligeo [Prescribing Information]. Bedminster, NJ: Kyowa Kirin; July 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 11/18
Client Approval: 03/21
P&T Approval: 10/18

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MOMETASONE SINUS IMPLANT (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOMETASONE FUROATE	SINUVA		44214	GPI-14 (42200045102350)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have non-self-administered (NSA) drug benefit coverage?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Has the patient previously had 4 implants (2 per nostril) per lifetime?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with an otolaryngologist
   - The patient previously had ethmoid sinus surgery
   - The patient is a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
   - The patient had a previous 90-day trial of **ONE** intranasal corticosteroid (e.g., fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 2 implants (1 per nostril).**
   APPROVAL TEXT: Renewal requires the patient has nasal polyps and has NOT had 4 implants (2 per nostril) per lifetime. In addition, the patient has ethmoid sinus polyps grade ≥ 1 on any side and does not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (grade 3 or 4).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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MOMETASONE SINUS IMPLANT (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an otolaryngologist (ear, nose and throat doctor)
D. You previously had ethmoid sinus surgery (process to remove blockage in your sinuses)
E. You are a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms (symptoms return and do not respond to surgery) of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
F. You previously had a 90-day trial of ONE intranasal corticosteroid (such as fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)
G. You have not received 4 implants (2 per nostril) in your lifetime

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Has the patient previously had 4 implants (2 per nostril) per lifetime?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?
   - The patient has ethmoid sinus polyps grade ≥ 1 on any side
   - The patient does **NOT** have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (grade 3 or 4)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 2 implants (1 per nostril). (Note: maximum #4 implants [2 per nostril] allowed per lifetime.)**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MOMETASONE SINUS IMPLANT (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You have ethmoid sinus polyps grade 1 or greater on any side
C. You do not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (scar tissue) (grade 3 or 4)
D. You have not previously received 4 implants (2 per nostril) in your lifetime

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sinuva.

REFERENCES

Sinuva [Prescribing Information]. Menlo Park, CA: Intersect ENT.; April 2020.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 10/01/20
Created: 05/18
Client Approval: 08/20
P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MONOMETHYL FUMARATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MONOMETHYL FUMARATE	BAFIERTAM	46576		GPI-10 (6240555000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Zeposia (ozanimod), fingolimod (Gilenya), dimethyl fumarate (Tecfidera), Vumerity (diroximel fumarate), Mayzent (siponimod)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Zeposia (ozanimod), fingolimod (Gilenya), dimethyl fumarate (Tecfidera), Vumerity (diroximel fumarate), Mayzent (siponimod)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bafiertam.

REFERENCES

Bafiertam [Prescribing Information]. High Point, NC: Banner Life Sciences LLC; September 2024.

Created: 11/20
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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MOSUNETUZUMAB-AXGB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOSUNETUZUMAB-AXGB	LUNSUMIO	48556		GPI-10 (2135205010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has tried two or more lines of systemic therapy

   If yes, **enter TWO approvals by HICL or GPI-10 for a total of 6 months as follows:**
   - **FIRST APPROVAL: Approve for 6 weeks for up to 4 fills with a quantity limit of #60 mL per fill.**
   - **SECOND APPROVAL: Approve for 18 weeks for 6 fills with a quantity limit of #30 mL per fill.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MOSUNETUZUMAB-AXGB (Lunsumio)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory follicular lymphoma (a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have tried two or more lines of systemic therapy (treatment that targets the entire body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MOSUNETUZUMAB-AXGB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma and meet **ALL** of the following criteria?
   - The patient has achieved a partial response to treatment
   - The patient has not previously received more than 17 cycles of treatment

   If yes, **approve for 7 months by HICL OR GPI-10 with a quantity limit of #30 mL per 21 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MOSUNETUZUMAB-AXGB (Lunsumio)** requires the following rule(s) be met for renewal:
   A. You have relapsed or refractory follicular lymphoma (a type of blood cancer that has returned or does not respond to treatment)
   B. You have achieved a partial response to treatment
   C. You have not previously received more than 17 cycles of treatment

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lunsumio.

REFERENCES
Lunsumio [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/01/23
Created: 01/23
Client Approval: 02/23
P&T Approval: 01/23

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MOTIXAFORTIDE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOTIXAFORTIDE ACETATE	APHEXDA	49205		GPI-10 (8250205010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) and meet **ALL** of the following criteria?
   - Aphexda will be used in combination with filgrastim or its biosimilars (e.g., Neupogen, Nivestym)
   - Aphexda will be used to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MOTIXAFORTIDE (Aphexda)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (MM: a type of blood cancer)
   B. Aphexda will be used in combination with filgrastim or its biosimilars (such as Neupogen, Nivestym)
   C. Aphexda will be used to mobilize hematopoietic stem cells to the peripheral blood for collection (a type of blood cell is stimulated to be collected from your blood) followed by autologous stem cell transplantation (a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aphexda.

REFERENCES

Aphexda [Prescribing Information]. Waltham, MA: BioLineRx USA Inc; September 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval: 10/23

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MOXETUMOMAB PASUDOTOX (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MOXETUMOMAB PASUDOTOX-TDFK	LUMOXITI	45363		GPI-10 (2135223650)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hairy cell leukemia (HCL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The disease is relapsed or refractory
   - The patient has received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received 6 cycles of Lumoxiti?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, **approve for 6 months by HICL or GPI-10.**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **MOXETUMOMAB PASUDOTOX (Lumoxiti)** requires the following rule(s) be met for approval:
A. You have hairy cell leukemia (HCL: type of blood and bone marrow cancer)
B. You are 18 years of age or older
C. You have relapsed or refractory disease (disease has returned or is not responsive to therapy)
D. You have received at least two prior systemic therapies, including treatment with a purine nucleoside analog (type of drug that treats certain blood cancers)
E. You have NOT previously received 6 cycles of Lumoxiti

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MOXETUMOMAB PASUDOTOX (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumoxiti.

REFERENCES

Lumoxiti [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 03/19
Client Approval: 03/21
P&T Approval: 01/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MYCOPHENOLATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MYCOPHENOLATE MOFETIL	MYHIBBIN		55684	GPI-14 (99403030101830)	

GUIDELINES FOR USE

1. Is the request for the prophylaxis of organ rejection and the patient meets **ALL** of the following criteria?
   - The patient has a history of an allogeneic kidney, heart or liver transplant
   - Myhibbin will be used in combination with other immunosuppressants (e.g., cyclosporine)
   - The patient had a trial of or contraindication to generic mycophenolate mofetil tablets
   - The patient is unable to swallow mycophenolate mofetil tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #15mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MYCOPHENOLATE (Myhibbin)** requires the following rule(s) be met for approval:
   A. The request is for the prophylaxis (prevention) of an organ rejection
   B. You have a history of an allogeneic (from a donor) kidney, heart or liver transplant
   C. Myhibbin will be used in combination with other immunosuppressants (such as cyclosporine)
   D. You have tried or have a contraindication to (harmful for you to use) generic mycophenolate mofetil tablets
   E. You are unable to swallow mycophenolate mofetil tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myhibbin.

REFERENCES

Myhibbin [Prescribing Information]. Middlesex, UK: Liqmeds Worldwide Limited; May 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 06/24
Client Approval: 06/24
P&T Approval: 10/24

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NAFARELIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NAFARELIN ACETATE	SYNAREL	21103		GPI-10 (3008005510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria (ICD-10 Group F64)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC NOTE: Please override the quantity limits coded on the formulary by selecting the "QL Only" override).**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis (ICD-10 Group N80 and R52) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an obstetrician/gynecologist
   - The patient had a trial of or contraindication to the clinical standard of care agents: a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
   - Synarel will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa [elagolix], Myfembree [relugolix-estradiol-norethindrone acetate], Lupron Depot [leuprolide])
   - The patient has NOT received more than 6 months of treatment with Synarel per lifetime

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #96mL per 6 months.**
   If no, continue to #3.

3. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.**
   If no, continue to #4.

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NAFARELIN

INITIAL CRITERIA (CONTINUED)

4. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - The patient has been evaluated for pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Moderate to severe pain from endometriosis (condition affecting the uterus)
      3. Central precocious puberty (CPP: early sexual development in girls and boys)

   B. If you have moderate to severe pain from endometriosis, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with an obstetrician/gynecologist (a type of women's health doctor)
      3. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medications: a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin- containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation)
      4. You are NOT using Synarel concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating agent (such as Orilissa [elagolix], Myfembree [relugolix-estradiol-norethindrone acetate], Lupron Depot [leuprolide])
      5. You have NOT received more than 6 months of treatment with Synarel per lifetime

   (Initial denial text continued on next page)

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NAFARELIN

INITIAL CRITERIA (CONTINUED)

C. If you are female and have central precocious puberty, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
4. You are/were younger than 8 years of age when your condition started
5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

D. If you are male and have central precocious puberty, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
4. You are/were younger than 9 years of age when your condition started
5. You have been evaluated for pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAFARELIN

RENEWAL CRITERIA

NOTE: For the diagnoses of gender dysphoria or pain from endometriosis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of central precocious puberty (CPP) (ICD-10 E30.1) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has NOT reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #32mL per month.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAFARELIN (Synarel)** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in girls and boys)
   B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have NOT reached the actual age which corresponds to your current pubertal age

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Synarel.

REFERENCES

Synarel [Prescribing Information]. New York, NY: Pfizer Inc.; November 2025.

Created: 09/18
Effective: 08/07/26 Client Approval: 08/26 DMC Approval: 08/04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NALTREXONE - BUPROPION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NALTREXONE HCL/ BUPROPION HCL	CONTRAVE	41389		GPI-10 (6125990250)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for weight loss OR weight management (ICD-10 Group E66) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - There is physician attestation of active enrollment in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)

   If yes, **approve for a total of 4 months by entering TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: #78 for 30 days.**
   - **SECOND APPROVAL: #4 per day for 3 months (please enter a start date of 3 days BEFORE the end of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NALTREXONE - BUPROPION

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NALTREXONE - BUPROPION (Contrave)** requires the following rule(s) be met for approval:

A. The request is for weight loss or weight management
B. You are 18 years of age or older
C. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
D. You meet ONE of the following before starting weight loss therapy:
    1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
    2. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
    3. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
    4. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])

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NALTREXONE - BUPROPION

RENEWAL CRITERIA

1. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Has the patient achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets twice daily)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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NALTREXONE - BUPROPION

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NALTREXONE - BUPROPION (Contrave)** requires the following rule(s) be met for renewal:

A. The request is for weight loss or weight management
B. You meet ONE of the following before starting weight loss therapy:
    1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
    2. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
    3. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
    4. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
C. You have achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets two times a day)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Contrave.

REFERENCES

Contrave [Prescribing Information]. San Diego, CA: Nalpropion Pharmaceuticals, Inc.; November 2025.

Created: 05/24
Effective: 04/10/26 Client Approval: 04/26 P&T Approval: 10/25

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NATALIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NATALIZUMAB	TYSABRI	26750		GPI-10 (6240505000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Tysabri will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Tysabri will be used as monotherapy
   - Tysabri will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of a relapsing form of MS
   - The patient had a trial of or contraindication to the preferred agent: Kesimpta (ofatumumab)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NATALIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

B. If you have moderate to severe Crohn's disease, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Tysabri concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz)
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

C. If you have a relapsing form of multiple sclerosis, approval also requires:
   1. You are 18 years of age or older
   2. Tysabri will be used as monotherapy (one drug treatment)
   3. You will NOT use Tysabri concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis (a type of nerve disorder)
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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NATALIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Tysabri will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient received at least 12 months of Tysabri therapy **AND** meets the following criterion?
   - The patient has NOT received more than 3 months of corticosteroids within the past 12 months for control of Crohn's disease while on Tysabri

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**
   If no, continue to #3.

3. Has the patient received only 6 months of Tysabri therapy **AND** meets the following criterion?
   - The patient is NOT currently on corticosteroids (the patient has tapered off corticosteroids during the first 6 months of Tysabri therapy)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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NATALIZUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - Tysabri will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of a relapsing form of MS

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NATALIZUMAB (Tysabri)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

   B. If you have moderate to severe Crohn's disease, renewal also requires:
      1. You will NOT use Tysabri concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
      2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         b. Skyrizi (risankizumab-rzaa)
         c. Tremfya (guselkumab)
         d. Omvoh (mirikizumab-mrkz)
         e. Adalimumab-ryvk/adalimumab-aaty
         f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

   (Renewal denial text continued on next page)

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NATALIZUMAB

RENEWAL CRITERIA (CONTINUED)

3. If you have received at least 12 months of Tysabri therapy, renewal also requires:
   a. You have NOT received more than 3 months of corticosteroids within the past 12 months to control your Crohn's disease while on Tysabri
4. If you have only received 6 months of Tysabri therapy, renewal also requires:
   a. You are NOT currently on corticosteroid therapy (you have slowly lowered the dose and stopped taking corticosteroids during the first 6 months of Tysabri therapy)

C. If you have a relapsing form of multiple sclerosis, renewal also requires:

1. You will NOT use Tysabri concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis (a type of nerve disorder)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Tysabri.

REFERENCES

Tysabri [Prescribing Information]. Cambridge, MA: Biogen Inc.; March 2025.

Created: 08/06
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 10/25

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NATALIZUMAB-SZTN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NATALIZUMAB-SZTN	TYRUKO	49170		GPI-10 (6240505070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Tyruko will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Tyruko will be used as monotherapy
   - Tyruko will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of a relapsing form of MS
   - The patient had a trial of or contraindication to the preferred agent: Kesimpta (ofatumumab)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NATALIZUMAB-SZTN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NATALIZUMAB-SZTN (Tyruko)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

B. If you have moderate to severe Crohn's disease, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

C. If you have a relapsing form of multiple sclerosis, approval also requires:
   1. You are 18 years of age or older
   2. Tyruko will be used as monotherapy (one drug treatment)
   3. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis (a type of nerve disorder)
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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NATALIZUMAB-SZTN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Tyruko will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient received at least 12 months of Tyruko therapy **AND** meets the following criterion?
   - The patient has NOT received more than 3 months of corticosteroids within the past 12 months for control of Crohn's disease while on Tyruko

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**
   If no, continue to #3.

3. Has the patient received only 6 months of Tyruko therapy **AND** meets the following criterion?
   - The patient is NOT currently on corticosteroids (the patient has tapered off corticosteroids during the first 6 months of Tyruko therapy)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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NATALIZUMAB-SZTN

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - Tyruko will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of a relapsing form of MS

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NATALIZUMAB-SZTN (Tyruko)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)

   B. If you have moderate to severe Crohn's disease, renewal also requires:
      1. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
      2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         b. Skyrizi (risankizumab-rzaa)
         c. Tremfya (guselkumab)
         d. Omvoh (mirikizumab-mrkz)
         e. Adalimumab-ryvk/adalimumab-aaty
         f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

3. If you have received at least 12 months of Tyruko therapy, renewal also requires:
   a. You have NOT received more than 3 months of corticosteroids within the past 12 months to control your Crohn's disease while on Tyruko
4. If you have only received 6 months of Tyruko therapy, renewal also requires:
   a. You are NOT currently on corticosteroid therapy (you have slowly lowered the dose and stopped taking corticosteroids during the first 6 months of Tyruko therapy)

C. If you have a relapsing form of multiple sclerosis, renewal also requires:

1. You will NOT use Tyruko concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis (a type of nerve disorder)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Tyruko and Tysabri.

REFERENCES

Tyruko [Prescribing Information]. Princeton, NJ: Sandoz Inc.; October 2025.
Tysabri [Prescribing Information]. Cambridge, MA: Biogen Inc.; March 2025.

Created: 10/25
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NAVEPEGRITIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NAVEPEGRITIDE	YUVIWEL	51182		GPI-10 (3095005500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of achondroplasia (ICD-10 Q77.4) and meet **ALL** of the following criteria?
   - The patient has open epiphyses
   - Therapy is prescribed by or in consultation with an endocrinologist, orthopedist, or medical geneticist
   - Yuviwel will NOT be used concurrently with another C-type natriuretic peptide (CNP) (e.g., Voxzogo [vosoritide]) for the treatment of achondroplasia

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAVEPEGRITIDE (Yuviwel)** requires the following rule(s) be met for approval:
   A. You have achondroplasia (a type of bone condition)
   B. You have open epiphyses (the end part of a long bone)
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), orthopedist (a type of doctor who specializes in bones, joints, muscles, ligaments, tendons and nerves), or medical geneticist (doctor who treats gene disorders)
   D. You will NOT use Yuviwel concurrently (at the same time) with another C-type natriuretic peptide (CNP) (such as Voxzogo [vosoritide]) for the treatment of achondroplasia (a type of bone condition)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NAVEPEGRITIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of achondroplasia (ICD-10 Q77.4) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in annual growth velocity since baseline
   - The patient's epiphyses remain open
   - Yuviwel will NOT be used concurrently with another C-type natriuretic peptide (CNP) (e.g., Voxzogo [vosoritide]) for the treatment of achondroplasia

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAVEPEGRITIDE (Yuviwel)** requires the following rule(s) be met for renewal:
   A. You have achondroplasia (a type of bone condition)
   B. You have experienced an improvement in annual growth velocity (rate of growth) since baseline (before treatment with Yuviwel)
   C. Your epiphyses (the end part of a long bone) remain open
   D. You will NOT use Yuviwel concurrently (at the same time) with another C-type natriuretic peptide (CNP) (such as Voxzogo [vosoritide]) for the treatment of achondroplasia (a type of bone condition)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yuviwel.

REFERENCES

Yuviwel [Prescribing Information]. Princeton, NJ: Ascendis Pharma Endocrinology, Inc.; February 2026.

Created: 03/26
Effective: 03/14/26 Client Approval: 03/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NAXITAMAB-GQGK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NAXITAMAB-GQGK	DANYELZA	47001		GPI-10 (2135605030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Danyelza will be used in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF)
   - The patient has demonstrated a partial response, minor response, or stable disease to prior therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NAXITAMAB-GQGK (Danyelza)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory high-risk neuroblastoma in the bone or bone marrow (a type of cancer that has returned or no longer responds to treatment)
   B. You are 1 year of age or older
   C. Danyelza will be used in combination with a granulocyte-macrophage colony-stimulating factor (GM-CSF) (a type of medication used to make more white blood cells)
   D. You have shown a partial response (the cancer partly responded to treatment, but still did not go away), minor response, or stable disease to prior therapy

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Danyelza.

REFERENCES

Danyelza [Prescribing Information]. Princeton, NJ: Y-mAbs Therapeutics, Inc.; August 2025.

Created: 02/21
Effective: 01/01/26 Client Approval:11/25 P&T Approval: 10/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NECITUMUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NECITUMUMAB	PORTRAZZA	42835		GPI-10 (2136005400)	

GUIDELINES FOR USE

1. Will necitumumab be used as a first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC) in combination with gemcitabine and cisplatin?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 vials per 21 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NECITUMUMAB (Portrazza)** requires the following rule(s) be met for approval:
   A. The medication will be used as a first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC; type of lung cancer that has spread to other parts of the body) in combination with gemcitabine and cisplatin

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Portrazza.

REFERENCES

Portrazza [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. May 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 12/15
Client Approval: 03/21
P&T Approval: 2/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NEDOSIRAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NEDOSIRAN SODIUM	RIVFLOZA	49234		GPI-10 (5662605060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary hyperoxaluria type 1 (PH1) (ICD-10 E72.53) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient has relatively preserved kidney function (e.g., eGFR is at least 30mL/min/1.73m[2])

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **80mg/0.5mL: #1mL per 30 days.**
   - **128mg/0.8mL: #0.8mL per 30 days.**
   - **160mg/mL: #1mL per 30 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NEDOSIRAN (Rivfloza)** requires the following rule(s) be met for approval:
   A. You have primary hyperoxaluria type 1 (PH1: a type of rare genetic disorder)
   B. You are 2 years of age or older
   C. You have relatively preserved kidney function (such as an estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] is at least 30mL/min/1.73m[2])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rivfloza.

REFERENCES

Rivfloza [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; March 2025.

Created: 01/24
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NEMOLIZUMAB-ILTO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NEMOLIZUMAB-ILTO	NEMLUVIO	49814		GPI-10 (9079355510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, immunologist, or allergist
   - The patient has the presence of multiple pruriginous lesions (localized or general)
   - The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (e.g., gabapentin, pregabalin), antidepressants (SNRI, SSRI, TCA), k-/mu-opioid receptor antagonists (e.g., naltrexone, butorphanol), thalidomide, topical corticosteroids, topical calcineurin inhibitors, topical calcipotriol, intralesional corticosteroids, phototherapy, methotrexate, cyclosporine, azathioprine
   - Nemluvio will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PN

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
   If no, continue to #2.

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NEMOLIZUMAB-ILTO

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Nemluvio will be used in combination with a topical corticosteroid (e.g., triamcinolone, clobetasol) and/or calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - The patient's disease is not adequately controlled with clinical standard of care topical prescription therapies (e.g., topical corticosteroids [e.g., hydrocortisone, clobetasol propionate, halobetasol propionate], topical PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Adquey (difamilast), Zoryve (roflumilast)], topical AhR agonist [e.g., Vtama (tapinarof)], topical JAK inhibitors [e.g., Opzelura (ruxolitinib)], topical calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]), with or without prior phototherapy
   - Nemluvio will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm]) and is switching to Nemluvio
   - The patient has atopic dermatitis covering at least 10% of body surface area (BSA)
   - The patient has atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, **approve 6 months by HICL or GPI-10 with a quantity limit of #1 per 28 days. (Please enter a one time approval for 1 month with a quantity limit of #2 per 28 days.)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NEMOLIZUMAB-ILTO

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **NEMOLIZUMAB-ILTO (Nemluvio)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Prurigo nodularis (PN: a type of skin condition)
   2. Moderate to severe atopic dermatitis (AD: a type of skin condition)

B. If you have prurigo nodularis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), immunologist (a type of immune system doctor), or allergist (a type of allergy doctor)
   3. You have multiple pruriginous lesions (wounds)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (such as gabapentin, pregabalin), antidepressants (serotonin-norepinephrine reuptake inhibitor [SNRI], selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant [TCA]), k-/mu-opioid receptor antagonists (such as naltrexone, butorphanol), thalidomide, topical corticosteroids (such as hydrocortisone), topical calcineurin inhibitors (such as Elidel [pimecrolimus]), topical calcipotriol, intralesional corticosteroids, phototherapy (light therapy), methotrexate, cyclosporine, azathioprine
   5. You will NOT use Nemluvio concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis (a type of skin condition)

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NEMOLIZUMAB-ILTO

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe atopic dermatitis, approval also requires:

1. You are 12 years of age or older
2. You will use Nemluvio in combination with a topical corticosteroid (such as triamcinolone, clobetasol) and/or calcineurin inhibitor (such as tacrolimus, pimecrolimus)
3. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
4. Your disease is not adequately controlled with clinical standard of care topical prescription therapies (such as topical corticosteroids [such as hydrocortisone, clobetasol propionate, halobetasol propionate], topical PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Adquey (difamilast), Zoryve (roflumilast)], topical aryl hydrocarbon receptor (AhR) agonist [such as Vtama (tapinarof)], topical JAK [Janus kinase] inhibitors [such as Opzelura (ruxolitinib)], topical calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)]), with or without prior phototherapy (light therapy)
5. You will NOT use Nemluvio concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)
6. You meet ONE of the following:
   a. You were previously stable on another biologic (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm]) and are switching to Nemluvio
   b. You have atopic dermatitis (a type of skin condition) covering at least 10% of body surface area (BSA)
   c. You have atopic dermatitis (a type of skin condition) affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)

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NEMOLIZUMAB-ILTO

RENEWAL CRITERIA

1. Does the patient have a diagnosis of prurigo nodularis (PN) (ICD-10 L28.1) and meet **ALL** of the following criteria?
   - The patient has had prurigo nodularis improvement (reduction) of pruritus or pruriginous lesions
   - Nemluvio will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PN

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on Nemluvio
   - Nemluvio will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 28 days.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **NEMOLIZUMAB-ILTO (Nemluvio)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Prurigo nodularis (PN: a type of skin condition)
      2. Moderate to severe atopic dermatitis (AD: a type of skin condition)

   B. If you have prurigo nodularis, renewal also requires:
      1. You have had prurigo nodularis improvement or reduction of pruritus (itching) or pruriginous lesions (wounds)
      2. You will NOT use Nemluvio concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of prurigo nodularis (a type of skin condition)

   C. If you have moderate to severe atopic dermatitis, renewal also requires:
      1. You have shown improvement while on Nemluvio
      2. You will NOT use Nemluvio concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

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NEMOLIZUMAB-ILTO

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nemluvio.

REFERENCES

Nemluvio [Prescribing Information]. Dallas, TX: Galderma Laboratories, L.P.; June 2025.

Created: 08/24
Effective: 07/15/26 DMC Approval: 06/29/26

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NERANDOMILAST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NERANDOMILAST	JASCAYD	50937		GPI-10 (4555505000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient does NOT have other known causes of interstitial lung disease (ILD) (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus [HIV] infection, viral hepatitis, cancer)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ofev (nintedanib), pirfenidone (Esbriet)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of progressive pulmonary fibrosis (PPF) (ICD-10 J84.170) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient has interstitial lung disease with a progressive phenotype (trait) (PF-ILD)
   - The patient's lung function and respiratory symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for ILD (not attributable to comorbidities [e.g., infection, heart failure])
   - The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing)
   - The patient had a trial of or contraindication to the preferred agent: Ofev (nintedanib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NERANDOMILAST

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NERANDOMILAST (Jascayd)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Idiopathic pulmonary fibrosis (IPF: a type of lung condition)
   2. Progressive pulmonary fibrosis (PPF: a type of lung condition with gradual scarring of the lungs)

B. If you have idiopathic pulmonary fibrosis, approval also requires:
   1. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
   2. You have a usual interstitial pneumonia (UIP) pattern (a specific type of lung scarring) as shown by high-resolution computed tomography (HRCT: type of imaging test) alone or by a combination of surgical lung biopsy (removal of cells or tissue from the lung for examination) and HRCT
   3. You do NOT have other known causes of interstitial lung disease (ILD: a type of lung condition) (such as connective tissue disease [a type of autoimmune disorder], drug toxicity, asbestos [a type of mineral that can be toxic] or beryllium [a type of metal that can be toxic] exposure, hypersensitivity pneumonitis [a type of lung condition], systemic sclerosis [a type of autoimmune disorder], rheumatoid arthritis [a type of joint condition], radiation, sarcoidosis [a type of inflammatory disorder], bronchiolitis obliterans organizing pneumonia [a type of lung condition], human immunodeficiency virus infection [HIV: an immune system disease caused by a virus], viral hepatitis [a type of liver inflammation], cancer)
   4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ofev (nintedanib), pirfenidone (Esbriet)

(Initial denial text continued on next page)

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NERANDOMILAST

INITIAL CRITERIA (CONTINUED)

C. If you have progressive pulmonary fibrosis, approval also requires:

1. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
2. You have interstitial lung disease with a progressive phenotype (trait) (PF-ILD)
3. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (not caused by comorbidities [additional health conditions] such as infection, heart failure)
4. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing) (such as reticular abnormality [a specific pattern on imaging studies] with traction bronchiectasis [a condition where the lungs' airway becomes damaged, widened, and thickened] with or without honeycombing)
5. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Ofev (nintedanib)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NERANDOMILAST

RENEWAL CRITERIA

1. Does the patient have ONE of the following diagnoses?
   - Idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112)
   - Progressive pulmonary fibrosis (PPF) (ICD-10 J84.170)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient experienced a clinically meaningful improvement or maintenance in annual rate of decline?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NERANDOMILAST (Jascayd)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Idiopathic pulmonary fibrosis (IPF: a type of lung condition)
      2. Progressive pulmonary fibrosis (PPF: a type of lung condition with gradual scarring of the lungs)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jascayd.

REFERENCES

Jascayd [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; December 2025.

Created: 10/25
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NERATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NERATINIB MALEATE	NERLYNX	44421		GPI-10 (2153303510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of early stage (stage I-III) breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is HER2-positive
   - Nerlynx will be used as extended adjuvant therapy following trastuzumab based therapy
   - Nerlynx is being requested within 2 years after completing last trastuzumab dose

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180 per 30 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 C79.81, Group C50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is HER2-positive
   - Nerlynx will be used in combination with capecitabine
   - The patient has received two or more prior anti-HER2 based regimens in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #180 per 30 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NERATINIB (Nerlynx)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Early stage (stage I-III) breast cancer
      2. Advanced or metastatic breast cancer (cancer that has spread to nearby tissue or has spread to other parts of the body)

   B. If you have early stage (stage I-III) breast cancer, approval also requires:
      1. You are 18 years of age or older
      2. Your tumor is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
      3. Nerlynx will be used as extended adjuvant (additional) therapy following trastuzumab based therapy
      4. Nerlynx is being requested within 2 years of completing the last trastuzumab dose

   (Denial text continued on next page)

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NERATINIB

GUIDELINES FOR USE (CONTINUED)

C. If you have advanced or metastatic breast cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumor is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
3. Nerlynx will be used in combination with capecitabine
4. You have received two or more prior anti-HER2 based regimens in the metastatic setting

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nerlynx.

REFERENCES

Nerlynx [Prescribing Information]. Los Angeles, CA: Puma Biotechnology; March 2024.

Created: 07/17
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NILOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NILOTINIB HCL	TASIGNA, NILOTINIB HCL	35149		GPI-10 (2153186020)	
NILOTINIB TARTRATE	DANZITEN	49984		GPI-10 (2153186060)	BRAND = DANZITEN

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) (ICD-10 Group C92.1)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's cancer newly diagnosed (e.g., starting or previously started nilotinib treatment at the time of diagnosis) and the patient meets **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient's cancer is in chronic phase

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day**.
   If no, continue to #3.

3. Has the patient's cancer been previously treated and the patient meets **ALL** of the following criteria?
   - The patient's cancer is in chronic phase or accelerated phase
   - The patient had a mutational analysis prior to initiation AND the requested medication is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NILOTINIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 1 to 17 years of age AND is resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) [e.g., Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)]
   - The patient is 18 years of age or older AND is resistant or intolerant to prior therapy that included imatinib (Gleevec)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NILOTINIB (Tasigna, Danziten)** requires the following rule(s) be met for approval:
   A. You have Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cell cancer)
   B. If your cancer is newly diagnosed (such as you are starting or previously started nilotinib treatment at the time your condition was identified), approval also requires:
      1. You are 1 year of age or older
      2. Your cancer is in chronic phase
   C. If your cancer has been previously treated, approval also requires:
      1. Your cancer is in chronic phase or accelerated phase
      2. You meet ONE of the following:
         a. You are 1 to 17 years of age AND you are resistant (not responding to treatment) or intolerant (side effect) to prior treatment with other tyrosine kinase inhibitors (TKIs, such as Gleevec [imatinib], Sprycel [dasatinib], Bosulif [bosutinib])
         b. You are 18 years of age or older AND you are resistant or intolerant to prior treatment that included Gleevec (imatinib)
      3. You had a mutational analysis (a type of lab test) prior to the start of treatment AND the requested medication is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1: a type of abnormal gene) profile

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NILOTINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tasigna, Danziten.

REFERENCES

Tasigna [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2024.
Danziten [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2024.

Created: 05/12
Effective: 02/25/26 Client Approval: 02/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIMODIPINE SOLUTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIMODIPINE	NYMALIZE, NIMODIPINE		34794 47984 47985 48405	GPI-14 (34000022002050) (34000022002054)	

GUIDELINES FOR USE

1. Does the patient have a history of subarachnoid hemorrhage (SAH) (ICD-10 I60.7) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient's SAH is from a ruptured intracranial berry aneurysm within the past 21 days
- The patient has a contraindication to or is unable to swallow generic nimodipine capsules

If yes, **approve the requested strength for 1 fill by GPID or GPI-14 up to a maximum 21-day supply with the following quantity limits:**
- **60mg/20mL: #120mL per day.**
- **30mg/5mL: #60mL per day.**
- **60mg/10mL: #60mL per day.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rule(s) be met for approval:
A. You have a history of a subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain)
B. You are 18 years of age or older
C. Your subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain) is from a ruptured intracranial berry aneurysm (part of blood vessel in your brain has expanded and burst) within the past 21 days
D. You have a contraindication to (harmful for you to use) or are unable to swallow generic nimodipine capsules

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nymalize.

REFERENCES

Nymalize (nimodipine solution) [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; August 2024.

Created: 08/13
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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NINTEDANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NINTEDANIB ESYLATE	OFEV	41489		GPI-10 (4555405020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient does NOT have other known causes of interstitial lung disease (ILD) (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus [HIV] infection, viral hepatitis, cancer)
   - Ofev will NOT be used concurrently with Esbriet

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   - The patient has a diagnosis of Systemic Sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT)
   - The patient has a baseline forced vital capacity (FVC) of at least 40% of predicted value
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) (e.g., heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors], recurrent aspiration [such as from GERD], pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage, ILD caused by another rheumatic disease such as mixed connective tissue disease [MCTD])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype (PF-ILD) (ICD-10 J84.170) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient's lung function and respiratory symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for ILD (not attributable to comorbidities [e.g., infection, heart failure])
   - The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT) (e.g., defined as reticular abnormality with traction bronchiectasis with or without honeycombing)
   - Ofev will NOT be used concurrently with Esbriet

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Idiopathic pulmonary fibrosis (IPF: a type of lung condition)
      2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      3. Chronic fibrosing interstitial lung disease with a progressive phenotype (PF-ILD: a type of lung condition with scarring of the lungs caused by different underlying diseases/conditions that worsen over time)

   B. If you have idiopathic pulmonary fibrosis, approval also requires:
      1. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
      2. You have a usual interstitial pneumonia pattern (UIP: a specific type of lung scarring) as shown by high-resolution computed tomography (HRCT: type of imaging test) alone or by a combination of surgical lung biopsy (removal of cells or tissue from the body for examination) and HRCT
      3. You do NOT have other known causes of interstitial lung disease (ILD: a type of lung condition) (such as connective tissue disease [a type of autoimmune disorder], drug toxicity, asbestos [a type of mineral that can be toxic] or beryllium [a type of metal that can be toxic] exposure, hypersensitivity pneumonitis [type of lung condition], systemic sclerosis [a type of autoimmune disorder], rheumatoid arthritis [a type of joint condition], radiation, sarcoidosis [a type of inflammatory disorder], bronchiolitis obliterans organizing pneumonia [a type of lung condition], human immunodeficiency virus [HIV: an immune system disease caused by a virus] infection, viral hepatitis [a type of liver inflammation], cancer)
      4. You will NOT use Ofev concurrently (at the same time) with Esbriet

   (Initial denial text continued on next page)

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

C. If you have systemic sclerosis-associated interstitial lung disease, approval also requires:

1. You have Systemic Sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
2. You are 18 years of age or older
3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
4. You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
5. You have a baseline (before treatment) forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40 percent of predicted value
6. You do NOT have other causes of interstitial lung disease (ILD: a type of lung condition) (such as heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors [class of blood pressure medications], recurrent aspiration [inhaling] such as from GERD [acid reflux], pulmonary vascular disease [affecting blood vessels in lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease [MCTD])

D. If you have chronic fibrosing interstitial lung disease with a progressive phenotype, approval also requires:

1. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
2. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (not caused by comorbidities [additional health conditions] such as infection, heart failure)
3. You have at least 10 percent fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing) (such as reticular abnormality [a specific pattern on imaging studies] with traction bronchiectasis [a condition where your lungs' airway becomes damaged, widened, and thickened] with or without honeycombing)
4. You will NOT use Ofev concurrently (at the same time) with Esbriet

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NINTEDANIB

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112)
   - Chronic fibrosing interstitial lung disease with a progressive phenotype (PF-ILD) (ICD-10 J84.170)

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline
   - Ofev will NOT be used concurrently with Esbriet

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) **AND** meet the following criterion?
   - The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NINTEDANIB (Ofev)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Idiopathic pulmonary fibrosis (IPF: a type of lung condition)
      2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
      3. Chronic fibrosing interstitial lung disease with a progressive phenotype (PF-ILD: a type of lung condition with scarring of the lungs caused by different underlying diseases/conditions that worsen over time)

   (Renewal denial text continued on next page)

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NINTEDANIB

RENEWAL CRITERIA (CONTINUED)

B. If you have idiopathic pulmonary fibrosis or chronic fibrosing interstitial lung disease with a progressive phenotype, renewal also requires:
1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
2. You will NOT use Ofev concurrently (at the same time) with Esbriet

C. If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:
1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ofev.

REFERENCES

Ofev [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; May 2025.

Created: 02/15
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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NIPOCALIMAB-AAHU

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIPOCALIMAB-AAHU	IMAAVY	50526		GPI-10 (9939825501)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient's diagnosis is confirmed by a positive serologic test for anti-acetylcholine receptor antibody (AChR-Ab+) OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+)
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to the clinical standard of care agent: ONE corticosteroid (e.g., prednisone)
   - Imaavy will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]), complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to the clinical standard of care agents: TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
   - The patient had a trial of or contraindication to the clinical standard of care agent: ONE non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 12 to 17 years of age
   - The patient is 18 years of age or older AND had a trial of or contraindication to ONE of the following preferred agents: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa- fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NIPOCALIMAB-AAHU

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of warm autoimmune hemolytic anemia (wAIHA) (ICD-10 D59.11) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient is currently being treated with or has previously been treated with corticosteroids (e.g., prednisone)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIPOCALIMAB-AAHU (Imaavy)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
      2. Warm autoimmune hemolytic anemia (wAIHA: a rare blood disorder)

   B. If you have generalized myasthenia gravis, approval also requires:
      1. You are 12 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
      3. Your diagnosis is confirmed by a positive serologic test (a type of blood test) for anti-acetylcholine receptor antibody (AChR-Ab+: an indicator of myasthenia gravis) OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+: an indicator of myasthenia gravis)
      4. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
      5. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE corticosteroid (such as prednisone)
      6. You will NOT use Imaavy concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

   (Initial denial text continued on the next page)

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NIPOCALIMAB-AAHU

INITIAL CRITERIA (CONTINUED)

7. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medications: TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
   b. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)
8. If you are 18 years of age or older, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)

C. If you have warm autoimmune hemolytic anemia, approval also requires:

1. You are 12 years of age or older
2. You are currently being treated with or have previously been treated with corticosteroids (such as prednisone)

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NIPOCALIMAB-AAHU

RENEWAL CRITERIA

NOTE: For the diagnosis of warm autoimmune hemolytic anemia (wAIHA), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Imaavy will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]), complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIPOCALIMAB-AAHU (Imaavy)** requires the following rule(s) be met for renewal:
   A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   B. You have shown a clinical benefit compared to baseline according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   C. You will NOT use Imaavy concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Rystiggo [rozanolixizumab-noli]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imaavy.

REFERENCES

Imaavy [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2026.

Created: 05/25
Effective: 09/04/26 Client Approval: 09/26 DMC Approval: 09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIRAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIRAPARIB TOSYLATE	ZEJULA	44177		GPI-10 (2153555020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the cancer advanced and does the patient meet **ALL** of the following criteria?
   - The patient is in complete or partial response to first-line platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The patient's cancer is associated with homologous recombination deficiency (HRD)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Is the cancer recurrent and does the patient meet **ALL** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA-mutation (gBRCAmut), based on an FDA-approved companion diagnostic for Zejula
   - The patient has completed at least TWO lines of platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The patient is in complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - Zejula will be started no later than 8 weeks after the patient's most recent platinum-containing regimen

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NIRAPARIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NIRAPARIB (Zejula)** requires the following rule(s) be met for approval:

A. You have advanced (has spread to other parts of the body) or recurrent (has returned) epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system or abdomen cancers)

B. If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:

1. You are 18 years of age or older
2. You are in complete or partial response (cancer is not detectable or has partly responded to treatment but still did not go away) to first-line platinum-based chemotherapy (such as cisplatin, carboplatin)
3. Your cancer is associated with homologous recombination deficiency (HRD: a type of gene mutation)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation (a type of gene mutation), and/or genomic instability (high rate of gene mutation)

C. If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:

1. You are 18 years of age or older
2. Your cancer has a deleterious or suspected deleterious germline BRCA-mutation (gBRCAmut: a type of gene mutation [abnormal change]) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Zejula
3. You have completed at least TWO lines of platinum-based chemotherapy (such as cisplatin, carboplatin)
4. You are in complete or partial response (cancer is not detectable or has partly responded to treatment but still did not go away) to platinum-based chemotherapy (such as cisplatin, carboplatin)
5. Zejula will be started no later than 8 weeks after your most recent platinum-containing regimen (such as cisplatin, carboplatin)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zejula.

REFERENCES

Zejula [Prescribing Information]. Durham, NC: GlaxoSmithKline; June 2025.

Created: 08/17
Effective: 08/04/25 Client Approval: 07/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIRAPARIB-ABIRATERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIRAPARIB-ABIRATERONE	AKEEGA	49143		GPI-10 (2140990212)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) and meet **ALL** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm) based on an FDA-approved test for Akeega
   - Akeega will be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)

   If yes, continue to #3.
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC) (ICD-10 Z19.1, C61) and meet **ALL** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious BRCA2 mutation (BRCA2m) based on an FDA-approved test for Akeega
   - Akeega will be used in combination with an oral corticosteroid (e.g., prednisone, prednisolone, methylprednisolone)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Akeega will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NIRAPARIB-ABIRATERONE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NIRAPARIB-ABIRATERONE (Akeega)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
   2. Metastatic castration-sensitive prostate cancer (mCSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

B. If you have metastatic castration-resistant prostate cancer, approval also requires:
   1. Your cancer has a deleterious (harmful) or suspected deleterious BRCA mutation (BRCAm: abnormal change in gene) based on a Food and Drug Administration (FDA)-approved test for Akeega
   2. Akeega will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
   3. You meet ONE of the following:
      a. You had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Akeega will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

C. If you have metastatic castration-sensitive prostate cancer, approval also requires:
   1. Your cancer has a deleterious (harmful) or suspected deleterious BRCA2 mutation (BRCA2m: abnormal change in gene) based on a Food and Drug Administration (FDA)- approved test for Akeega
   2. Akeega will be used in combination with an oral corticosteroid (such as prednisone, prednisolone, methylprednisolone)
   3. You meet ONE of the following:
      a. You had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Akeega will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NIRAPARIB-ABIRATERONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Akeega.

REFERENCES

Akeega [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; December 2025.

Created: 10/23
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIROGACESTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIROGACESTAT HYDROBROMIDE	OGSIVEO	49323		GPI-10 (2153235020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of progressing desmoid tumors (ICD-10 Group D48.11) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient requires systemic treatment

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **50mg: #6 per day.**
   - **100mg: #2 per day.**
   - **150mg: #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIROGACESTAT (Ogsiveo)** requires the following rule(s) be met for approval:
   A. You have progressing desmoid tumors (noncancerous growths in the connective tissue)
   B. You are 18 years of age or older
   C. You require systemic treatment (treatment that targets the entire body)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ogsiveo.

REFERENCES

Ogsiveo [Prescribing Information]. Stamford, CT: SpringWorks Therapeutics, Inc.; April 2024.

Created: 12/23
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIRSEVIMAB-ALIP (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIRSEVIMAB-ALIP	BEYFORTUS	49077		GPI-10 (1950205205)	

GUIDELINES FOR USE

1. Is the request for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease and the patient meets **ONE** of the following criteria?
   - The patient is less than 12 months of age (neonate or infant) and born during or entering their first RSV season
   - The patient is 12 to 24 months of age and remains vulnerable to severe RSV disease

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has not completed a course of Synagis (palivizumab) and will not receive further doses of Synagis within the same RSV season
   - The patient has not received a dose of Synagis in the past 30 days, and will not receive further doses of Synagis within the same RSV season

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient received 2 doses of Beyfortus in their lifetime?

   If yes, continue to #4.
   If no, continue to #7.

4. Has the patient undergone or will undergo cardiac surgery with cardiopulmonary bypass?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the patient requesting a zero-dollar cost share exception (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #6.
   If no, **approve for 6 months by HICL or GPI-10 for 1 fill.**

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NIRSEVIMAB-ALIP (NSA)

GUIDELINES FOR USE (CONTINUED)

6. Is the patient 19 months of age or younger?

   If yes, **approve for 6 months by GPID or GPI-14 at zero copay for a total of 1 fill for the requested strength as follows:**
   - **50mg/0.5mL: #0.5 mL.**
   - **100mg/1mL: #2 mL.**

   If no, **approve for 6 months by HICL or GPI-10 for 1 fill.**

7. Is the patient requesting a zero-dollar cost share exception (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #9.
   If no, continue to #8.

8. Has the patient undergone or will undergo cardiac surgery with cardiopulmonary bypass?

   If yes, **approve for 6 months by HICL or GPI-10 for 2 fills.**
   If no, **approve for 6 months by HICL or GPI-10 for 1 fill.**

9. Is the patient 19 months of age or younger?

   If yes, **approve for 6 months by GPID or GPI-14 at zero copay for a total of 1 fill for the requested strength as follows:**
   - **50mg/0.5mL: #0.5 mL.**
   - **100mg/1mL: #2 mL.**

   If no, continue to #10.

10. Has the patient undergone or will undergo cardiac surgery with cardiopulmonary bypass?

    If yes, **approve for 6 months by HICL or GPI-10 for 2 fills.**
    If no, **approve for 6 months by HICL or GPI-10 for 1 fill.**

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NIRSEVIMAB-ALIP (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NIRSEVIMAB-ALIP (Beyfortus)** requires the following rule(s) be met for approval:

A. Beyfortus will be used for the prevention of respiratory syncytial virus (RSV: a type of lung and respiratory tract infection)
B. You meet ONE of the following:
   1. You are less than 12 months of age (neonate or infant), and you were born during or are entering your first RSV season (period of increased rate of infection)
   2. You are 12 to 24 months of age and are vulnerable to (at risk of) severe RSV disease
C. You have NOT completed a course of Synagis (palivizumab) within this RSV season or you have not received a dose of Synagis in the past 30 days, AND you will not receive further doses of Synagis within this RSV season
D. You have not received more than 2 doses of Beyfortus in your lifetime, unless you have undergone or will undergo a cardiac surgery with cardiopulmonary bypass (a type of heart and lung surgery)
E. Requests for zero dollar cost share also requires that you are 19 months of age or younger

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Beyfortus.

REFERENCES

Beyfortus [Prescribing Information]. AstraZeneca AB: Södertälje, Sweden; July 2023.
Centers for Disease Control and Prevention (CDC) (2023, November 2). *RSV Regional Trends - NREVSS*. Centers for Disease Control and Prevention. https://www.cdc.gov/surveillance/nrevss/rsv/region.html

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NITISINONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NITISINONE	ORFADIN, NITYR, NITISINONE	23253		GPI-10 (3090404500)	BRAND ≠ HARLIKU

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary tyrosinemia type 1 (HT-1) (ICD-10 E70.21) and meet **ALL** of the following criteria?
   - The patient has elevated urinary or plasma succinylacetone (SA) levels OR a mutation in the fumarylacetoacetate hydrolase (FAH) gene
   - Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases
   - The patient has been counseled on maintaining dietary restriction of tyrosine and phenylalanine

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for generic nitisinone capsules?

   If yes, **approve all strengths of generic nitisinone capsules for 6 months by GPID-G or GPI-14-G.**

   If no, continue to #3.

3. Is the request for Nityr tablets **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to generic nitisinone capsules

   If yes, **approve for 6 months by NDC for all strengths or by GPI-10.**
   If no, continue to #4.

4. Is the request for brand Orfadin capsules or Orfadin oral suspension, **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to generic nitisinone capsules

   If yes, **approve the requested formulation for 6 months by GPID for all strengths or by GPI-10.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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NITISINONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for approval:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder)
B. You have elevated urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) OR a mutation (abnormal change) in the fumarylacetoacetate hydrolase gene
C. Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases
D. You have been counseled on maintaining dietary restriction of tyrosine and phenylalanine
E. If you are requesting Nityr tablets; brand Orfadin capsules; or Orfadin oral suspension, approval also requires:
    1. You have tried or have a contraindication to (harmful for you to use) generic nitisinone capsules

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NITISINONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary tyrosinemia type 1 (HT-1) (ICD-10 E70.21) **AND** meet the following criterion?
- The patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the renewal request for generic nitisinone capsules?

If yes, **approve all strengths of generic nitisinone capsules for 12 months by GPID-G or GPI-14-G.**

If no, continue to #3.

3. Is the renewal request for Nityr tablets?

If yes, **approve for 12 months by NDC for all strengths or by GPI-10.**
If no, continue to #4.

4. Is the renewal request for brand Orfadin capsules or Orfadin oral suspension?

If yes, **approve the requested formulation for 12 months by GPID for all strengths or by GPI-10.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for renewal:
A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder)
B. Your urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) have decreased from baseline while on treatment with nitisinone

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NITISINONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orfadin and Nityr.

REFERENCES

Orfadin [Prescribing Information]. Waltham, MA: Sobi, Inc.; November 2021.
Nityr [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd.; May 2024.

Created: 08/16
Effective: 08/04/25 Client Approval: 07/25 P&T Approval: 07/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NITISINONE-HARLIKU

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NITISINONE	HARLIKU	23253		GPI-10 (3090225500)	BRAND = HARLIKU

GUIDELINES FOR USE

1. Does the patient have a diagnosis of alkaptonuria (AKU) (ICD-10 E70.29) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Harliku will be used to reduce the level of urine homogentisic acid (HGA)

   If yes, **approve for 12 months by NDC or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NITISINONE-HARLIKU** requires the following rule(s) be met for approval:
   A. You have alkaptonuria (AKU: a type of rare genetic disorder)
   B. You are 18 years of age or older
   C. Harliku will be used to reduce the level of urine homogentisic acid (HGA) (a type of lab test)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Harliku.

REFERENCES

Harliku [Prescribing Information]. Cambridge, United Kingdom: Cycle Pharmaceuticals Ltd; June 2025.

Created: 07/25
Effective: 08/04/25 Client Approval: 07/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NITROFURANTOIN SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/ Other
NITROFURANTOIN	FURADANTIN, NITROFURANTOIN		41870	GPI-14 (16800050001810)	

GUIDELINES FOR USE

1. Is the request for the treatment of a urinary tract infection (UTI) (ICD-10 N39.0) and the patient meets **ALL** of the following criteria?
   - The infection is caused by susceptible strains of *Escherichia coli, enterococci, Staphylococcus aureus, Klebsiella,* or *Enterobacter* species
   - The patient has a contraindication to or is unable to swallow nitrofurantoin capsules

   If yes, **approve for 30 days by GPID or GPI-14 with a quantity limit #560mL per 7 days for #1 fill.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NITROFURANTOIN (Furadantin)** requires the following rule(s) be met for approval:
   A. You have a urinary tract infection (UTI: a type of infection)
   B. Your infection is caused by susceptible (can be treated with the drug) strains of *Escherichia coli, enterococci, Staphylococcus aureus, Klebsiella* or *Enterobacter* species (types of bacteria)
   C. You have a contraindication to (harmful for you to use) or are not able to swallow nitrofurantoin capsules

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Furadantin.

REFERENCES

Furadantin (nitrofurantoin oral suspension) [Prescribing Information]. East Brunswick, NJ: Casper Pharma LLC; February 2024.

Created: 07/24
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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NIVOLUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIVOLUMAB	OPDIVO	41654		GPI-10 (2135794100)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Opdivo will be used as a single agent OR in combination with Yervoy (ipilimumab)
   - Opdivo will NOT be used concurrently with targeted therapy (i.e., BRAF inhibitors [Braftovi (encorafenib), Tafinlar (dabrafenib)], MEK inhibitors [Mekinist (trametinib)], and NTRK inhibitors [Vitrakvi (larotrectinib), Rozlytrek (entrectinib)])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of stage IIB, IIC, III, or IV melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has undergone complete resection
   - Opdivo will be used as an adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of resectable (node positive or tumor is 4 cm or greater) non- small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #4.
   If no, continue to #6.

4. Will Opdivo be used in combination with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment only?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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NIVOLUMAB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - The patient's cancer has no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements
   - Opdivo will be used in combination with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery and prior use with platinum-doublet chemotherapy as neoadjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #7.
   If no, continue to #10.

7. Does the patient's tumors express PD-L1 (at least 1 percent), as determined by an FDA-approved test, and meet **ALL** of the following criteria?
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations
   - Opdivo will be used in combination with Yervoy (ipilimumab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

8. Will Opdivo be used in combination with Yervoy (ipilimumab) and 2 cycles of platinum-doublet chemotherapy (e.g., carboplatin/pemetrexed, cisplatin/pemetrexed, carboplatin/paclitaxel) **AND** the patient meets the following criterion?
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

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GUIDELINES FOR USE (CONTINUED)

9. Has the patient's disease progressed while on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and the patient meets **ONE** of the following criteria?
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations
   - The tumor has an ALK mutation, and the patient had disease progression following an FDA- approved ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])
   - The tumor has an EGFR mutation, and the patient had disease progression following an FDA- approved EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

10. Does the patient have a diagnosis of recurrent non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The tumor does NOT have EGFR or ALK genomic tumor aberrations
    - Opdivo will be used in combination with Yervoy (ipilimumab) AND 2 cycles of platinum-doublet chemotherapy (e.g., carboplatin/pemetrexed, cisplatin/pemetrexed, carboplatin/paclitaxel)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #11.

11. Does the patient have a diagnosis of unresectable malignant pleural mesothelioma (ICD-10 C45.0) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo will be used in combination with Yervoy (ipilimumab)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #12.

12. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #13.
    If no, continue to #14.

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NIVOLUMAB

GUIDELINES FOR USE (CONTINUED)

13. Does the patient meet **ONE** of the following criteria?
    - The patient has intermediate or poor risk disease AND Opdivo will used in combination with Yervoy (ipilimumab)
    - Opdivo will be used in combination with Cabometyx (cabozantinib)
    - The patient has received prior anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib], Cabometyx [cabozantinib])

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

14. Does the patient have a diagnosis of classical Hodgkin lymphoma (cHL) (ICD-10 Group C81)?

    If yes, continue to #15.
    If no, continue to #19.

15. Has the patient's disease been previously treated?

    If yes, continue to #16.
    If no, continue to #18.

16. Has the patient's disease relapsed or progressed after **ONE** of the following?
    - Autologous hematopoietic stem cell transplantation (HSCT) and Adcetris (brentuximab vedotin)
    - 3 or more lines of systemic therapy that includes autologous HSCT

    If yes, continue to #17.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

17. Is the patient 18 years of age or older?

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

18. Is the patient's disease Stage III or IV and the patient meets **ALL** of the following criteria?
    - The patient is 12 years of age or older
    - Opdivo will be used in combination with doxorubicin, vinblastine, and dacarbazine (AVD)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

19. Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has disease progression while on or after treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #20.

20. Does the patient have a diagnosis of urothelial carcinoma (UC) (ICD-10 Groups C65, C66, C67, C68) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo will be used as an adjuvant treatment
    - The patient is at high risk of recurrence after undergoing radical resection of UC

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #21.

21. Does the patient have a diagnosis of unresectable or metastatic urothelial carcinoma (UC) (ICD-10 Groups C65, C66, C67, C68) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo will be used in combination with cisplatin and gemcitabine

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #22.

22. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (UC) (ICD-10 Groups C65, C66, C67, C68) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #23.
    If no, continue to #24.

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NIVOLUMAB

GUIDELINES FOR USE (CONTINUED)

23. Does the patient meet **ONE** of the following criteria?
    - The patient has disease progression during or following platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

24. Does the patient have a diagnosis of colorectal cancer (CRC) (ICD-10 C19) and meet **ALL** of the following criteria?
    - The patient is 12 years of age or older
    - The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

    If yes, continue to #25.
    If no, continue to #27.

25. Is the patient's cancer unresectable **AND** the patient meets the following criterion?
    - Opdivo will be used in combination with Yervoy (ipilimumab)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #26.

26. Is the patient's cancer metastatic and the patient meets **ONE** of the following criteria?
    - Opdivo will be used in combination with Yervoy (ipilimumab)
    - Opdivo will be used as a single agent, AND the patient has disease progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

27. Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ONE** of the following criteria?
    - Opdivo will be used in combination with Yervoy (ipilimumab) as first-line treatment
    - Opdivo will be used in combination with Yervoy (ipilimumab), AND the patient has been previously treated with Nexavar (sorafenib)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #28.

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GUIDELINES FOR USE (CONTINUED)

28. Does the patient have a diagnosis of completely resected esophageal or gastroesophageal junction cancer (ICD-10 C16.0; Group C15) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo will be used as an adjuvant treatment
    - The patient has a residual pathologic disease and has received neoadjuvant chemoradiotherapy (CRT)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #29.

29. Does the patient have a diagnosis of unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has received prior fluoropyrimidine- and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #30.

30. Does the patient have a diagnosis of unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #31.
    If no, continue to #32.

31. Does the patient meet **ONE** of the following criteria?
    - Opdivo will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - Opdivo will be used in combination with Yervoy (ipilimumab)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

32. Does the patient have a diagnosis of advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (ICD-10 Groups C15, C16) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **NIVOLUMAB (Opdivo)** requires the following rule(s) be met for approval:
    A. You have ONE of the following:
        1. Unresectable or metastatic melanoma (type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
        2. Stage IIB, IIC, III, or IV melanoma (a type of skin cancer)
        3. Resectable (node positive or tumor is 4 cm or greater) non-small cell lung cancer (NSCLC) (a type of lung cancer that can be removed by surgery)
        4. Metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to other parts of the body)
        5. Recurrent non-small cell lung cancer (NSCLC) (a type of lung cancer that has returned)
        6. Unresectable malignant pleural mesothelioma (a tumor of the tissue lining the lungs and chest wall that cannot be removed by surgery)
        7. Advanced renal cell carcinoma (RCC: type of kidney cancer)
        8. Classical Hodgkin lymphoma (cHL: a type of blood cancer)
        9. Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN: type of head/neck cancer that has returned or spread to other parts of the body)
        10. Urothelial carcinoma (UC: urinary system cancer)
        11. Unresectable or metastatic urothelial carcinoma (urinary system cancer that cannot be removed by surgery or has spread to other parts of the body)
        12. Locally advanced or metastatic urothelial carcinoma (urinary system cancer that has spread to nearby tissue or lymph nodes or that has spread to other parts of the body)
        13. Colorectal cancer (a type of digestive cancer)
        14. Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be removed by surgery or has spread to other parts of the body)

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GUIDELINES FOR USE (CONTINUED)

15. Completely resected esophageal or gastroesophageal junction cancer (types of digestive system cancer that has been removed by surgery)
16. Unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC: type of digestive system cancer that cannot be removed by surgery, and has returned or has spread to other parts of the body)
17. Unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC: type of digestive system cancer that cannot be removed by surgery and has spread to other parts of the body)
18. Advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (types of digestive system cancer that has spread to other parts of the body)

B. If you have unresectable or metastatic melanoma, approval also requires:
1. You are 12 years of age or older
2. Opdivo will be used alone OR in combination with Yervoy (ipilimumab)
3. Opdivo will NOT be used concurrently (at the same time) with a targeted therapy (BRAF inhibitors [such as Braftovi (encorafenib), Tafinlar (dabrafenib)], MEK inhibitors [such as Mekinist (trametinib)], and NTRK inhibitors [such as Vitrakvi (larotrectinib), Rozlytrek (entrectinib)])

C. If you have stage IIB, IIC, III, or IV melanoma, approval also requires:
1. You are 12 years of age or older
2. You have undergone complete resection (completely removed by surgery)
3. Opdivo will be used as an adjuvant (add-on) treatment

D. If you have resectable (node positive or tumor is 4 cm or greater) non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Opdivo will be used in combination with platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment (given before main treatment) only
   b. Your cancer has NO known epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements (type of gene mutation); AND Opdivo will be used in combination with platinum-doublet chemotherapy (such as carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment (given before main treatment), OR as a single medication as adjuvant (add-on) treatment after surgery and prior use with platinum-doublet chemotherapy as neoadjuvant treatment

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GUIDELINES FOR USE (CONTINUED)

E. If you have metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your tumors have programmed death-ligand 1 (PD-L1: a type of protein [of at least 1 percent]) as determined by a Food and Drug Administration (FDA)-approved test; your tumor does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of enzyme) genomic tumor aberrations (types of abnormal gene); AND Opdivo will be used in combination with Yervoy (ipilimumab)
   b. Your tumor does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of enzyme) genomic tumor aberrations (types of abnormal gene) AND Opdivo will be used in combination with Yervoy (ipilimumab) and 2 cycles of platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/pemetrexed, cisplatin/pemetrexed, carboplatin/paclitaxel)
   c. Your disease has worsened while on or after platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin), and you meet ONE of the following:
      i. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of enzyme) genomic tumor aberrations (types of abnormal gene)
      ii. Your tumor has an ALK mutation, and your disease has worsened after treatment with an FDA-approved ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
      iii. Your tumor has an EGFR mutation, and your disease has worsened after treatment with an FDA-approved EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

F. If you have recurrent non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumor does NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of enzyme) genomic tumor aberrations (types of abnormal gene)
3. Opdivo will be used in combination with Yervoy (ipilimumab) AND 2 cycles of platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/pemetrexed, cisplatin/pemetrexed, carboplatin/paclitaxel)

G. If you have unresectable malignant pleural mesothelioma, approval also requires:
1. You are 18 years of age or older
2. Opdivo will be used in combination with Yervoy (ipilimumab)

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NIVOLUMAB

GUIDELINES FOR USE (CONTINUED)

H. If you have advanced renal cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have intermediate or poor risk disease AND Opdivo will used in combination with Yervoy (ipilimumab)
   b. Opdivo will be used in combination with Cabometyx (cabozantinib)
   c. You have received prior anti-angiogenic therapy (medication that stop tumors from growing their own blood vessels such as Sutent [sunitinib], Votrient [pazopanib], Cabometyx [cabozantinib])

I. If you have classical Hodgkin lymphoma, approval also requires ONE of the following:
1. If your disease has been previously treated, you meet ALL of the following:
   a. You are 18 years of age or older
   b. Your disease has relapsed (returned) or worsened after receiving ONE of the following:
      i. Autologous hematopoietic stem cell transplantation (HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells) and Adcetris (brentuximab vedotin)
      ii. Three or more lines of systemic therapy (treatment that targets the entire body) that includes autologous hematopoietic stem cell transplantation (HSCT: a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)
2. If your disease has NOT been previously treated, you meet ALL of the following:
   a. You are 12 years of age or older
   b. Your disease is Stage III or IV
   c. Opdivo will be used in combination with doxorubicin, vinblastine, and dacarbazine (AVD)

J. If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:
1. You are 18 years of age or older
2. Your disease has worsened on or after treatment with a platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

K. If you have urothelial carcinoma, approval also requires:
1. You are 18 years of age or older
2. Opdivo will be used as an adjuvant (add-on) treatment
3. You are at high risk of recurrence (disease returning) after undergoing radical resection (tumor removal) of urothelial carcinoma

L. If you have unresectable or metastatic urothelial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You will be using Opdivo in combination with cisplatin and gemcitabine

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NIVOLUMAB

GUIDELINES FOR USE (CONTINUED)

M. If you have locally advanced or metastatic urothelial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your disease has worsened during or after platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
   b. Your disease has worsened within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

N. If you have colorectal cancer, approval also requires:
1. You are 12 years of age or older
2. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities)
3. You meet ONE of the following:
   a. Your cancer is unresectable (cannot be removed by surgery); AND Opdivo will be used in combination with Yervoy (ipilimumab)
   b. Your cancer is metastatic (has spread to other parts of the body), and you meet ONE of the following:
      i. Opdivo will be used in combination with Yervoy (ipilimumab)
      ii. Opdivo will be used as a single medication; AND your disease has worsened after treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

O. If you have unresectable or metastatic hepatocellular carcinoma, approval also requires ONE of the following:
1. You will be using Opdivo in combination with Yervoy (ipilimumab) as first-line treatment
2. You will be using Opdivo in combination with Yervoy (ipilimumab), AND you have been previously treated with Nexavar (sorafenib)

P. If you have completely resected esophageal or gastroesophageal junction cancer, approval also requires:
1. You are 18 years of age or older
2. Opdivo will be used as an adjuvant (add-on) treatment
3. You have a residual pathologic disease (disease is still present) and have received neoadjuvant chemoradiotherapy (CRT) (a type of cancer treatment given before surgery)

Q. If you have unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You have previously received treatment with fluoropyrimidine- and platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

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NIVOLUMAB

GUIDELINES FOR USE (CONTINUED)

R. If you have unresectable advanced or metastatic esophageal squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You will be using Opdivo in combination with fluoropyrimidine- and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
   b. You will be using Opdivo in combination with Yervoy (ipilimumab)

S. If you have advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. You will be using Opdivo in combination with fluoropyrimidine and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Opdivo.

REFERENCES
Opdivo [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2026.

Created: 05/15
Effective: 05/09/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB-HYALURONIDASE-NVHY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIVOLUMAB-HYALURONIDASE-NVHY	OPDIVO QVANTIG	50124		GPI-10 (2199000250)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has intermediate or poor risk disease, and Opdivo Qvantig will be used following treatment with intravenous Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
   - Opdivo Qvantig will be used in combination with Cabometyx (cabozantinib)
   - The patient has received prior anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib])

   If yes, **approve the 600mg strength for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, continue to #4.
   If no, continue to #6.

4. Is the patient's cancer unresectable or metastatic?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **300mg-5,000units/2.5mL: #5mL per 28 days.**
   - **600mg-10,000units/5mL: #10mL per 28 days.**

   If no, continue to #5.

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GUIDELINES FOR USE (CONTINUED)

5. Is the patient's cancer stage IIB, IIC, III, or IV and the patient meets **ALL** of the following criteria?
   - The patient has undergone complete resection
   - Opdivo Qvantig will be used as an adjuvant treatment

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **300mg-5,000units/2.5mL: #5mL per 28 days.**
   - **600mg-10,000units/5mL: #10mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is resectable (node positive or tumor is at least 4cm)

   If yes, continue to #7.
   If no, continue to #11.

7. Will Opdivo Qvantig be used in combination with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **300mg-5,000units/2.5mL: #2.5mL per 21 days.**
   - **600mg-10,000units/5mL: #10mL per 21 days.**

   If no, continue to #8.

8. Does the patient's cancer have no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements?

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

9. Will Opdivo Qvantig be used in combination with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **300mg-5,000units/2.5mL: #2.5mL per 21 days.**
   - **600mg-10,000units/5mL: #10mL per 21 days.**

   If no, continue to #10.

10. Will Opdivo Qvantig be used as monotherapy as adjuvant treatment **AND** the patient meets the following criterion?
    - The patient had surgical resection and prior use with platinum-doublet chemotherapy (e.g., carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment

    If yes, **approve the 600mg strength for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has disease progression while on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, continue to #12.
    If no, continue to #13.

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GUIDELINES FOR USE (CONTINUED)

12. Does the patient meet **ONE** of the following criteria?
    - The tumor does NOT have EGFR or ALK genomic aberrations
    - The tumor has an EGFR mutation, and the patient had disease progression following an FDA- approved EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])
    - The tumor has an ALK mutation, and the patient had disease progression following an FDA- approved ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])

    If yes, **approve the 600mg strength for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

13. Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has disease progression while on or after treatment with a platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve the 600mg strength for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 28 days.**

    If no, continue to #14.

14. Does the patient have a diagnosis of urothelial carcinoma (UC) (ICD-10 Groups C65, C66, C67, C68) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #15.
    If no, continue to #18.

15. Is the patient at high risk of recurrence after undergoing radical resection of urothelial carcinoma **AND** meets the following criterion?
    - Opdivo Qvantig will be used as an adjuvant treatment

    If yes, **approve the 600mg strength for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 28 days.**

    If no, continue to #16.

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GUIDELINES FOR USE (CONTINUED)

16. Is the patient's cancer unresectable or metastatic **AND** the patient meets the following criterion?
    - Opdivo Qvantig will be used in combination with cisplatin and gemcitabine

    If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
    - **300mg-5,000units/2.5mL: #2.5mL per 21 days.**
    - **600mg-10,000units/5mL: #10mL per 21 days.**

    If no, continue to #17.

17. Is the patient's cancer locally advanced or metastatic and the patient meets **ONE** of the following criteria?
    - The patient has disease progression during or following platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve the 600mg strength for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

18. Does the patient have a diagnosis of colorectal cancer (CRC) (ICD-10 C19) and meet **ALL** of the following criteria?
    - The patient is 12 years of age or older
    - The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

    If yes, continue to #19.
    If no, continue to #21.

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GUIDELINES FOR USE (CONTINUED)

19. Is the patient's cancer metastatic and the patient meets **ONE** of the following criteria?
    - Opdivo Qvantig will be used following treatment with intravenous Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
    - The patient has disease progression following treatment with a fluoropyrimidine (e.g., fluorouracil, capecitabine), oxaliplatin, and irinotecan

    If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
    - **300mg-5,000units/2.5mL: #5mL per 28 days.**
    - **600mg-10,000units/5mL: #10mL per 28 days.**

    If no, continue to #20.

20. Is the patient's cancer unresectable **AND** the patient meets the following criterion?
    - Opdivo Qvantig will be used following treatment with intravenous Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy

    If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
    - **300mg-5,000units/2.5mL: #5mL per 28 days.**
    - **600mg-10,000units/5mL: #10mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

21. Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo Qvantig will be used following treatment with intravenous Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy

    If yes, **approve the 600mg strength for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 28 days.**

    If no, continue to #22.

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GUIDELINES FOR USE (CONTINUED)

22. Does the patient have a diagnosis of esophageal or gastroesophageal junction cancer (ICD-10 C16.0; Group C15) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has undergone complete resection
    - Opdivo Qvantig will be used as an adjuvant treatment
    - The patient has a residual pathologic disease
    - The patient has received neoadjuvant chemoradiotherapy (CRT)

    If yes, **approve the 600mg strength for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 28 days.**

    If no, continue to #23.

23. Does the patient have a diagnosis of esophageal squamous cell carcinoma (ESCC) (ICD-10 Group C15) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #24.
    If no, continue to #26.

24. Is the patient's cancer unresectable advanced or metastatic and the patient meets **ALL** of the following criteria?
    - Opdivo Qvantig will be used in combination with fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient's tumors express PD-L1 (at least 1%)

    If yes, **approve the 600mg strength for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 28 days.**

    If no, continue to #25.

25. Is the patient's cancer unresectable advanced, recurrent or metastatic **AND** the patient meets the following criterion?
    - The patient has received prior fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve the 600mg strength for 12 months by GPID or GPI-14 with a quantity limit of #10mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

26. Does the patient have a diagnosis of advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (ICD-10 Groups C15, C16) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Opdivo Qvantig will be used in combination with fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient's tumors express PD-L1 (at least 1%)

    If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
    - **300mg-5,000units/2.5mL: #2.5mL per 21 days.**
    - **600mg-10,000units/5mL: #10mL per 21 days.**

    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **NIVOLUMAB-HYALURONIDASE-NVHY (Opdivo Qvantig)** requires the following rule(s) be met for approval:

    A. You have ONE of the following:
        1. Advanced renal cell carcinoma (RCC) (a type of kidney cancer)
        2. Melanoma (a type of skin cancer)
        3. Non-small cell lung cancer (NSCLC) (a type of lung cancer)
        4. Metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to other parts of the body)
        5. Recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (a type of head/neck cancer that has returned or has spread to other parts of the body)
        6. Urothelial carcinoma (UC: urinary system cancer)
        7. Colorectal cancer (CRC) (a type of digestive cancer)
        8. Unresectable or metastatic hepatocellular carcinoma (HCC: a type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)
        9. Esophageal or gastroesophageal junction cancer (types of digestive system cancer)
        10. Esophageal squamous cell carcinoma (ESCC) (a type of digestive system cancer)
        11. Advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (types of digestive system cancer that has spread to other parts of the body)

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GUIDELINES FOR USE (CONTINUED)

B. If you have advanced renal cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have intermediate or poor risk disease, and Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
   b. Opdivo Qvantig will be used in combination with Cabometyx (cabozantinib)
   c. You have received prior anti-angiogenic therapy (a type of medication that stops tumors from growing new blood vessels, such as Sutent [sunitinib], Votrient [pazopanib])

C. If you have melanoma, approval also requires:
1. You are 12 years of age or older
2. You meet ONE of the following:
   a. Your cancer is unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body)
   b. Your cancer is stage IIB, IIC, III, or IV; you have undergone complete resection (removal by surgery); and Opdivo Qvantig will be used as an adjuvant (add-on) treatment

D. If you have non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your cancer is resectable (node positive or tumor is at least 4 cm) (can be removed by surgery)
3. You meet ONE of the following:
   a. Opdivo Qvantig will be used in combination with platinum-doublet chemotherapy (a type of cancer treatment, such as carboplatin/paclitaxel, cisplatin/pemetrexed, cisplatin/gemcitabine) as neoadjuvant treatment (given before main treatment)
   b. Your cancer has no known epidermal growth factor receptor (EGFR: a type of protein) mutations (abnormal change in a type of gene) or anaplastic lymphoma kinase (ALK: a type of enzyme) rearrangements (type of gene mutation), and you meet ONE of the following:
      i. Opdivo Qvantig will be used in combination with platinum-doublet chemotherapy (such as carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment (given before main treatment)
      ii. Opdivo Qvantig will be used alone as adjuvant (add-on) treatment after surgical resection (removal by surgery) and prior use with platinum-doublet chemotherapy (such as carboplatin/paclitaxel, cisplatin/pemetrexed, carboplatin/pemetrexed, cisplatin/docetaxel) as neoadjuvant treatment (given before main treatment)

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GUIDELINES FOR USE (CONTINUED)

E. If you have metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your disease has worsened while on or after platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin), and you meet ONE of the following:
   a. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of enzyme) genomic aberrations (types of abnormal gene)
   b. Your tumor has an epidermal growth factor receptor (EGFR: type of protein) mutation (abnormal change in a type of gene), and your disease has worsened after treatment with a Food and Drug Administration (FDA)-approved EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])
   c. Your tumor has an anaplastic lymphoma kinase (ALK: type of enzyme) mutation (abnormal change in a type of gene), and your disease has worsened after treatment with a Food and Drug Administration (FDA)-approved ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])

F. If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:
1. You are 18 years of age or older
2. Your disease has worsened while on or after treatment with a platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

G. If you have urothelial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You are at high risk of recurrence (disease returning) after undergoing radical resection (tumor removal) of urothelial carcinoma (UC: urinary system cancer), and Opdivo Qvantig will be used as an adjuvant (add-on) treatment
   b. Your cancer is unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body), and Opdivo Qvantig will be used in combination with cisplatin and gemcitabine
   c. Your cancer is locally advanced (has spread to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body), and you meet ONE of the following:
      i. Your disease has worsened during or following platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
      ii. Your disease has worsened within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

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GUIDELINES FOR USE (CONTINUED)

H. If you have colorectal cancer, approval also requires:
1. You are 12 years of age or older
2. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities)
3. You meet ONE of the following:
   a. You have metastatic cancer (cancer that has spread to other parts of the body) and meet ONE of the following:
      i. Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy
      ii. Your disease has worsened after treatment with a fluoropyrimidine (a type of cancer treatment, such as fluorouracil, capecitabine), oxaliplatin, and irinotecan
   b. You have unresectable cancer (cancer that cannot be removed by surgery) and Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy

I. If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:
1. You are 18 years of age or older
2. Opdivo Qvantig will be used following treatment with intravenous (injection into the vein) Opdivo (nivolumab) and Yervoy (ipilimumab) combination therapy

J. If you have esophageal or gastroesophageal junction cancer, approval also requires:
1. You are 18 years of age or older
2. You have undergone complete resection (removal by surgery)
3. Opdivo Qvantig will be used as an adjuvant (add-on) treatment
4. You have a residual pathologic disease (disease is still present)
5. You have received neoadjuvant chemoradiotherapy (CRT) (a type of cancer treatment given before surgery)

K. If you have esophageal squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your cancer is unresectable (cannot be removed by surgery) advanced or metastatic (has spread to other parts of the body); Opdivo Qvantig will be used in combination with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin); AND your tumor expresses programmed death-ligand 1
   (PD-L1: type of protein) (at least 1%)
   b. Your cancer is unresectable (cannot be removed by surgery) advanced, recurrent (has returned) or metastatic (has spread to other parts of the body), AND you have previously received treatment with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)

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GUIDELINES FOR USE (CONTINUED)

L. If you have advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Opdivo Qvantig will be used in combination with fluoropyrimidine- (a type of cancer treatment, such as fluorouracil, capecitabine) and platinum-containing chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin, oxaliplatin)
3. Your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) (at least 1%)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Opdivo Qvantig.

REFERENCES
Opdivo Qvantig [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb; November 2025.

Created: 01/25
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 01/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIVOLUMAB-RELATLIMAB-RMBW (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIVOLUMAB-RELATLIMAB-RMBW	OPDUALAG	47910		GPI-10 (2199350250)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #40 mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NIVOLUMAB-RELATLIMAB-RMBW (Opdualag)** requires the following rule(s) be met for approval:
   A. You have unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
   B. You are 12 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opdualag.

REFERENCES

Opdualag [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NOGAPENDEKIN ALFA (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NOGAPENDEKIN ALFA INBAKICEPT-PMLN	ANKTIVA	49543		GPI-10 (2170305565)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (ICD-10 D09.0 and Group C67) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is unresponsive to Bacillus Calmette-Guérin (BCG)
   - Anktiva will be used in combination with Bacillus Calmette-Guérin (BCG)

   If yes, **approve for 40 months total by HICL or GPI-10 with a quantity limit of #1.6mL per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NOGAPENDEKIN ALFA (Anktiva)** requires the following rule(s) be met for approval:
   A. You have non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (a type of early stage bladder cancer)
   B. You are 18 years of age or older
   C. Your cancer did not respond to treatment with Bacillus Calmette-Guérin (BCG: a type of bladder cancer treatment)
   D. Anktiva will be used together with Bacillus Calmette-Guérin (BCG: a type of bladder cancer treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Anktiva.

REFERENCES

Anktiva [Prescribing Information]. Culver City, CA: ImmunityBio, Inc.; April 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 05/13/24
Created: 04/24
Client Approval: 05/24
P&T Approval: 07/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NUSINERSEN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NUSINERSEN SODIUM/PF	SPINRAZA	44016		GPI-10 (7470005000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) (ICD-10 G12.9) and meet **ALL** of the following criteria?
- The patient's diagnosis of spinal muscular atrophy (SMA) is confirmed by gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1) gene (e.g., homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [i.e., deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
- Therapy is prescribed by or in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient pre-symptomatic **AND** meets the following criterion?
- The patient has up to (i.e., no more than) three copies of the survival motor neuron 2 (SMN2) gene based on newborn screening

If yes, **please enter TWO approvals for a total of 6 months by HICL or GPI-10 as follows:**
- **FIRST APPROVAL: approve for 1 month for 3 fills with a quantity limit of #5mL per fill.**
- **SECOND APPROVAL: approve for 5 months for 2 fills with a quantity limit of #5mL per fill (Please enter a start date of 2 weeks AFTER the end date of the first approval).**

If no, continue to #3.

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NUSINERSEN (NSA)

INITIAL CRITERIA (CONTINUED)

3. Is the patient symptomatic and meets **ALL** of the following criteria?
   - The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
   - The patient has had a baseline motor function assessment by a neuromuscular specialist or SMA specialist
   - If the patient has received prior gene therapy, they had a less than expected clinical benefit with gene therapy

   If yes, **please enter TWO approvals for a total of 6 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 1 month for 3 fills with a quantity limit of #5mL per fill.**
   - **SECOND APPROVAL: approve for 5 months for 2 fills with a quantity limit of #5mL per fill (Please enter a start date of 2 weeks AFTER the end date of the first approval).**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **NUSINERSEN (Spinraza)** requires the following rule(s) be met for approval:

   A. You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
   B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by a gene mutation analysis indicating mutations (abnormal changes) or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
   C. Therapy is prescribed by or in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
   D. If you are pre-symptomatic (symptoms have not yet appeared), approval also requires:
      1. You have up to (no more than) three copies of the survival motor neuron 2 (SMN2: type of protein in spinal cord) gene based on screening that was done when you were a newborn

   (Initial denial text continued on the next page)

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NUSINERSEN (NSA)

INITIAL CRITERIA (CONTINUED)

E. If you are symptomatic (symptoms have appeared), approval also requires:

1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
2. You had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
3. If you previously had gene therapy, you experienced a less than expected clinical benefit with gene therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NUSINERSEN (NSA)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) (ICD-10 G12.9) and meet **ONE** of the following criteria?

- The patient has improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline (e.g., HINE, HFMSE, CHOP-INTEND)
- The patient has improved, maintained, or demonstrated a less than expected decline in other muscle function (e.g., pulmonary)

If yes, **approve for 12 months by HICL or GPI-10 for 3 fills with a quantity limit of #5mL per fill.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NUSINERSEN (Spinraza)** requires the following rule(s) be met for renewal:

A. You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
B. You meet ONE of the following:
    1. You have improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE), and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    2. You have improved, maintained, or demonstrated a less than expected decline in other muscle function (such as pulmonary [lung/breathing] function)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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NUSINERSEN (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spinraza.

REFERENCES

Spinraza [Prescribing Information]. Cambridge, MA: Biogen, Inc.; April 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/17
Client Approval: 06/24
P&T Approval: 04/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBETICHOLIC ACID

Generic	Brand	HICL	GCN	MEDISPAN	Exception/Other
OBETICHOLIC ACID	OCALIVA	43438		GPI-10 (5275006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) as confirmed by at least **TWO** of the following criteria?
   - The patient has an elevated alkaline phosphatase (ALP) level
   - The patient has the presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210 if AMA is negative
   - The patient has histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does not have cirrhosis OR has compensated cirrhosis with no evidence of portal hypertension
   - Therapy is prescribed by or in consultation with a gastroenterologist or hepatologist
   - The patient does NOT have complete biliary obstruction
   - Ocaliva will NOT be used concurrently with any other second-line PBC treatment (i.e., Iqirvo [elafibranor], Livdelzi [seladelpar])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - Ocaliva will be used as monotherapy in a patient who is unable to tolerate ursodiol (ursodeoxycholic acid)
   - Ocaliva will be used in combination with ursodiol (ursodeoxycholic acid) in a patient who had an inadequate response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OBETICHOLIC ACID

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), as confirmed by TWO of the following:
   1. You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   2. You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210 if AMA is negative
   3. You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)
B. You are 18 years of age or older
C. You do not have cirrhosis (liver damage and scarring) OR you have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) with no evidence of portal hypertension (high blood pressure in the major vein that leads to the liver)
D. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)
E. You do NOT have complete biliary obstruction (blockage of bile ducts)
F. You will NOT use Ocaliva concurrently (at the same time) with any other second-line therapy for PBC (Iqirvo [elafibranor], Livdelzi [seladelpar])
G. You meet ONE of the following:
   1. Ocaliva will be used as monotherapy (one drug treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
   2. Ocaliva will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one drug treatment)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OBETICHOLIC ACID

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC) (ICD-10 K74.3) and meet **ALL** of the following criteria?
   - The patient has an alkaline phosphatase (ALP) level that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Ocaliva
   - The patient has NOT developed complete biliary obstruction
   - Ocaliva will NOT be used concurrently with any other second-line PBC treatment (i.e., Iqirvo [elafibranor], Livdelzi [seladelpar])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for renewal:
   A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct)
   B. You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67-times the upper limit of normal AND which has decreased by at least 15 percent from baseline while on treatment with Ocaliva
   C. You have NOT developed complete biliary obstruction (blockage of bile ducts)
   D. You will NOT use Ocaliva concurrently (at the same time) with any other second-line therapy for PBC (Iqirvo [elafibranor], Livdelzi [seladelpar])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ocaliva.

REFERENCES

Ocaliva [Prescribing Information]. Morristown, NJ: Intercept Pharmaceuticals, Inc.; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/16/24
Created: 08/16
Client Approval: 09/24
P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBINUTUZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OBINUTUZUMAB	GAZYVA	40703		GPI-10 (2135184300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient has not received previous treatment for CLL
   - Gazyva will be used in combination with Leukeran (chlorambucil)

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of follicular lymphoma (FL) (ICD-10 Group C82)?

   If yes, continue to #3.
   If no, continue to #10.

3. Has the patient relapsed after, or is refractory to, a regimen containing rituximab?

   If yes, continue to #4.
   If no, continue to #6.

4. Will Gazyva be used in combination with bendamustine for the initial six cycles?

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #5.

5. Will Gazyva be used as monotherapy following initial combination therapy with bendamustine?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is the patient's cancer stage II bulky, III or IV and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has NOT received previous treatment for stage II bulky, III or IV follicular lymphoma

   If yes, continue to #7.
   If no, continue to #9.

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OBINUTUZUMAB

GUIDELINES FOR USE (CONTINUED)

7. Will Gazyva be used in combination with chemotherapy (e.g., bendamustine; CHOP [cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone]; CVP [cyclophosphamide, vincristine, prednisone or prednisolone]) for the initial six or eight cycles?

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #8.

8. Will Gazyva be used as monotherapy following initial combination therapy with chemotherapy?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Is the patient's cancer relapsed or refractory **AND** Gazyva will be used in combination with Brukinsa (zanubrutinib)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

10. Will Gazyva be used as a pretreatment prior to initiating Columvi (glofitamab-gxbm)?

    If yes, **approve for 1 month by HICL or GPI-10 for 1 fill.**
    If no, continue to #11.

11. Does the patient have a diagnosis of lupus nephritis (LN) (ICD-10 M32.14) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient is receiving standard therapy (e.g., mycophenolate mofetil and corticosteroids)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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OBINUTUZUMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OBINUTUZUMAB (Gazyva)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Chronic lymphocytic leukemia (CLL: a type of blood and bone marrow cancer)
   2. Follicular lymphoma (FL: a type of cancer with abnormal immune cells)
   3. Use as a pretreatment prior to initiating Columvi (glofitamab-gxbm)
   4. Lupus nephritis (a type of immune condition that affects the kidneys)

B. If you have chronic lymphocytic leukemia, approval also requires:
   1. You have NOT received previous treatment for chronic lymphocytic leukemia
   2. Gazyva will be used in combination with Leukeran (chlorambucil)

C. If you have follicular lymphoma, approval also requires ONE of the following:
   1. You have relapsed after or are refractory to (disease has returned or is resistant to) a regimen containing rituximab; AND Gazyva will be used in combination with bendamustine for the initial six cycles OR as monotherapy (the only drug used in treatment) thereafter
   2. Your cancer is stage II bulky, III, or IV; you are 18 years of age or older; you have NOT received previous treatment for stage II bulky, III or IV follicular lymphoma; AND Gazyva will be used in combination with chemotherapy (such as bendamustine; CHOP [cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone]; CVP [cyclophosphamide, vincristine, prednisone or prednisolone]) for the initial six or eight cycles, or as monotherapy (the only drug used in treatment) thereafter
   3. You have relapsed or refractory follicular lymphoma (disease has returned or is resistant to treatment); AND Gazyva will be used in combination with Brukinsa (zanubrutinib)

D. If you have lupus nephritis, approval also requires:
   1. You are 18 years of age or older
   2. You are receiving standard therapy (such as mycophenolate mofetil and corticosteroids)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OBINUTUZUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gazyva, Columvi, or Brukinsa.

REFERENCES

Gazyva [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; October 2025.
Columvi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2025.
Brukinsa [Prescribing Information]. San Mateo, CA: BeiGene USA, Inc.; March 2024.

Created: 11/13
Effective: 12/01/25 Client Approval: 11/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCRELIZUMAB AND OCRELIZUMAB-HYALURONIDASE-OCSQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCRELIZUMAB	OCREVUS	44178		GPI-10 (6240506000)	
OCRELIZUMAB-HYALURONIDASE-OCSQ	OCREVUS ZUNOVO	49868		GPI-10 (6240990260)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary progressive multiple sclerosis (PPMS) (ICD-10 G35) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
   - **Ocrevus: #20mL per 6 months.**
   - **Ocrevus Zunovo: #23mL per 6 months.**

   If no, continue to #2.

2. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the preferred agent: Kesimpta (ofatumumab)

   If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
   - **Ocrevus: #20mL per 6 months.**
   - **Ocrevus Zunovo: #23mL per 6 months.**

   If no, continue to #3.

3. Does the patient have a diagnosis of relapsing-remitting multiple sclerosis (MS) (ICD-10 G35.A) **AND** meet the following criterion?
   - The request is for Ocrevus (ocrelizumab)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OCRELIZUMAB AND OCRELIZUMAB-HYALURONIDASE-OCSQ

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following?
   - The patient is 10 to 17 years of age
   - The patient is 18 years of age or older AND had a trial of or contraindication to the preferred agent: Kesimpta (ofatumumab)

   If yes, **approve Ocrevus for 12 months by HICL or GPI-10 with a quantity limit of #20mL per 6 months.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCRELIZUMAB AND OCRELIZUMAB-HYALURONIDASE-OCSQ (Ocrevus, Ocrevus Zunovo)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Primary progressive multiple sclerosis (PPMS: a type of nerve disorder)
      2. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
      3. Relapsing-remitting multiple sclerosis (MS) (a type of nerve disorder that returns and goes away)

   B. If you have primary progressive multiple sclerosis, approval also requires:
      1. You are 18 years of age or older

   C. If you have a relapsing form of multiple sclerosis, approval also requires:
      1. You are 18 years of age or older
      2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

   D. If you have relapsing-remitting multiple sclerosis, approval also requires:
      1. The request is for Ocrevus (ocrelizumab)
      2. You meet ONE of the following:
         a. You are 10 to 17 years of age
         b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

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OCRELIZUMAB AND OCRELIZUMAB-HYALURONIDASE-OCSQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Ocrevus and Ocrevus Zunovo.

REFERENCE

Ocrevus [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2026.
Ocrevus Zunovo [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2025.

Created: 01/17
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - IM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE, MI-SPHERES	SANDOSTATIN LAR DEPOT, OCTREOTIDE ACETATE ER	19000		GPI-12 (301700701064)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had an inadequate response to surgery or radiotherapy, OR surgery or radiotherapy is not an option for this patient
   - The patient's serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patient's age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load
   - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **10mg: #1 per 28 days.**
   - **20mg: #2 per 28 days.**
   - **30mg: #1 per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes (ICD-10 R19.7, R23.2) associated with metastatic carcinoid tumors (ICD-10 Groups C7B.0, C7A.0, D3A.0) **AND** meet the following criterion?
   - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve for 2 months by HICL or GPI-12 with a quantity limit of #1 per 28 days.**
   If no, continue to #3.

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OCTREOTIDE - IM

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPoma) (ICD-10 C25.4) **AND** meet the following criterion?
   - The patient had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   If yes, **approve for 2 months by HICL or GPI-12 with a quantity limit of #1 per 28 days.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Acromegaly (a type of hormone disorder)
      2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to other parts of the body)
      3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (a type of tumor that starts from hormone producing cells)

   B. If you have acromegaly, approval also requires:
      1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
      2. You had an inadequate response (did not work) to surgery or radiotherapy (a type of cancer treatment), OR surgery or radiotherapy is not an option for you
      3. Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
      4. You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   C. If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:
      1. You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   D. If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors, approval also requires:
      1. You had a prior response to and tolerated subcutaneous octreotide injection for at least 2 weeks

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OCTREOTIDE - IM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or has sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **10mg: #1 per 28 days.**
   - **20mg: #2 per 28 days.**
   - **30mg: #1 per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes (ICD-10 R19.7, R23.2) associated with metastatic carcinoid tumors (ICD-10 Groups C7B.0, C7A.0, D3A.0) **AND** meet the following criterion?
   - The patient has shown improvement or has sustained remission of clinical symptoms

   If yes, **approve for 12 months by HICL or GPI-12 with a quantity limit of #1 per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPoma) (ICD-10 C25.4) **AND** meet the following criterion?
   - The patient has shown improvement or has sustained remission of clinical symptoms

   If yes, **approve for 12 months by HICL or GPI-12 with a quantity limit of #1 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OCTREOTIDE - IM

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - IM (Sandostatin LAR Depot)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Acromegaly (a type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to other parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (a type of tumor that starts from hormone producing cells)

B. If you have acromegaly, renewal also requires:
   1. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   2. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

C. If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, renewal also requires:
   1. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms

D. If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors, renewal also requires:
   1. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sandostatin LAR Depot.

REFERENCES

Sandostatin LAR Depot [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals Corporation; July 2024.

Created: 08/22
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - ORAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE	MYCAPSSA		48334	GPI-14 (30170070106520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has responded to and tolerated treatment with octreotide or lanreotide
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patient's age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for approval:
   A. You have acromegaly (a type of hormone disorder)
   B. You have responded to and tolerated treatment with octreotide or lanreotide
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - ORAL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or has sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OCTREOTIDE - ORAL (Mycapssa)** requires the following rule(s) be met for renewal:
   A. You have acromegaly (a type of hormone disorder)
   B. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   C. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mycapssa.

REFERENCES

Mycapssa [Prescribing Information]. Scotland, UK: MW Encap Ltd.; July 2024.

Created: 08/20
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE	BYNFEZIA		47454	GPI-14 (3017007010D220)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patient's age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load
   - The patient had a trial of or contraindication to the preferred agent: a generic octreotide (e.g., octreotide acetate)
   - The patient had an inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes (ICD-10 R19.7, R23.2) associated with metastatic carcinoid tumors (ICD-10 Groups C7B.0, C7A.0, D3A.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the preferred agent: a generic octreotide (e.g., octreotide acetate)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas) (ICD-10 C25.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the preferred agent: a generic octreotide (e.g., octreotide acetate)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OCTREOTIDE - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Acromegaly (a type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. If you have acromegaly, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a generic octreotide (such as octreotide acetate)
   5. You had an inadequate response (did not work) to or cannot be treated with surgical resection (removal by surgery), pituitary irradiation (radiation therapy directed at the pituitary), and bromocriptine mesylate at maximally tolerated doses

C. If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a generic octreotide (such as octreotide acetate)

D. If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas), approval also requires:
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a generic octreotide (such as octreotide acetate)

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OCTREOTIDE - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has a reduction, normalization or maintenance of IGF-1 levels based on age and gender
   - The patient has shown an improvement or sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of severe diarrhea and flushing episodes (ICD-10 R19.7, R23.2) associated with metastatic carcinoid tumors (ICD-10 Groups C7B.0, C7A.0, D3A.0) **AND** meet the following criterion?
   - The patient has improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas) (ICD-10 C25.4) **AND** meet the following criterion?
   - The patient has improvement or sustained remission of clinical symptoms

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16.8mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OCTREOTIDE - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Acromegaly (a type of hormone disorder)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. If you have acromegaly, renewal also requires:
   1. You have had a reduction, normalization or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   2. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

C. If you have severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, renewal also requires:
   1. You have an improvement or sustained remission (reduction or disappearance) of clinical symptoms

D. If you have profuse watery diarrhea associated with vasoactive intestinal peptide (VIP)-secreting tumors (VIPomas), renewal also requires:
   1. You have an improvement or sustained remission (reduction or disappearance) of clinical symptoms

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bynfezia.

REFERENCES

Bynfezia [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc.; September 2024.

Created: 08/20
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ODEVIXIBAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ODEVIXIBAT	BYLVAY	47501		GPI-10 (5235006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cholestatic pruritus (ICD-10 L29.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and the patient meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in PFIC cholestasis
   - Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 3 months to 11 months of age
   - The patient is 12 months of age or older AND had a trial of or contraindication to the preferred agent: Livmarli (maralixibat)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **200mcg pellets: #30 per day.**
   - **400mcg capsule: #15 per day.**
   - **600mcg pellets: #10 per day.**
   - **1200mcg capsule: #5 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ODEVIXIBAT

INITIAL CRITERIA (CONTINUED)

4. Is the patient's pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and the patient meets **ALL** of the following criteria?
   - The patient is 12 months of age or older
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or physician who specializes in ALGS cholestasis
   - Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])
   - The patient had a trial of or contraindication to the preferred agent: Livmarli (maralixibat)

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **200mcg pellets: #36 per day.**
   - **400mcg capsule: #18 per day.**
   - **600mcg pellets: #12 per day.**
   - **1200mcg capsule: #6 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)
      2. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

   B. If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, approval also requires:
      1. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in PFIC cholestasis
      2. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])
      3. You meet ONE of the following:
         a. You are 3 months to 11 months of age
         b. You are 12 months of age or older AND have tried or have a contraindication to (harmful for you to use) the preferred medication: Livmarli (maralixibat)

   (Initial denial text continued on the next page)

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ODEVIXIBAT

INITIAL CRITERIA (CONTINUED)

C. If you have cholestatic pruritus associated with Alagille syndrome, approval also requires:

1. You are 12 months of age or older
2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (a doctor who treats digestive conditions), or physician (doctor) who specializes in ALGS cholestasis
3. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Livmarli (maralixibat)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ODEVIXIBAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cholestatic pruritus (ICD-10 L29.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient's pruritus associated with progressive familial intrahepatic cholestasis (PFIC) and the patient meets **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline
   - The patient does NOT have PFIC type 2 with specific ABCB11 variants that would result in nonfunctional, or the complete absence of, bile salt export pump (BSEP) protein
   - Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **200mcg pellets: #30 per day.**
   - **400mcg capsule: #15 per day.**
   - **600mcg pellets: #10 per day.**
   - **1200mcg capsule: #5 per day.**

   If no, continue to #3.

3. Is the patient's pruritus associated with Alagille syndrome (ALGS) (ICD-10 Q44.71) and the patient meets **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as improvement in pruritus symptoms AND a reduction of serum bile acid from baseline
   - Bylvay will NOT be used concurrently with another IBAT inhibitor (e.g., Livmarli [maralixibat])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **200mcg pellets: #36 per day.**
   - **400mcg capsule: #18 per day.**
   - **600mcg pellets: #12 per day.**
   - **1200mcg capsule: #6 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ODEVIXIBAT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Cholestatic pruritus (itching caused by liver disease) associated with progressive familial intrahepatic cholestasis (PFIC: a type of genetic disorder)
   2. Cholestatic pruritus (itching caused by liver disease) associated with Alagille syndrome (ALGS: a type of genetic disorder)

B. If you have cholestatic pruritus associated with progressive familial intrahepatic cholestasis, renewal also requires:
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Bylvay)
   2. You do NOT have PFIC type 2 with specific ABCB11 variants (a type of abnormal gene) that would result in nonfunctional (does not work), or the complete absence of, bile salt export pump (BSEP: a type of protein)
   3. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

C. If you have cholestatic pruritus associated with Alagille syndrome, renewal also requires:
   1. You have shown a clinical response to therapy, defined as improvement in pruritus (itching) symptoms AND a reduction of serum bile acid (a type of blood test) from baseline (before starting Bylvay)
   2. You will NOT use Bylvay concurrently (at the same time) with another ileal bile acid transporter (IBAT) inhibitor (such as Livmarli [maralixibat])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bylvay.

REFERENCES

Bylvay [Prescribing Information]. Boston, MA: Albireo Pharma, Inc.; March 2025.

Created: 10/21
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 04/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OFATUMUMAB	ARZERRA		27827	GPI-10 (2135184500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient previously untreated for chronic lymphocytic leukemia (CLL) and meets **ALL** of the following criteria?
   - Fludara (fludarabine)-based therapy is considered inappropriate in this patient
   - The requested medication will be used in combination with chlorambucil

   If yes, **approve as follows by GPID or GPI-14 and enter two prior authorizations:**
   - **FIRST APPROVAL:**
     - **Approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials**
   - **SECOND APPROVAL (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**
     - **Approve 12 months of Arzerra 100mg/5mL with a quantity limit of #10 vials per 28 days (total fill count of 12) OR**
     - **Approve 12 months of Arzerra 1,000mg/50mL with a quantity limit of #1 vial per 28 days (total fill count of 12)**

   If no, continue to #3.

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OFATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for the treatment of **relapsed** chronic lymphocytic leukemia (CLL) **AND** does the patient meet the following criterion?
   - The requested medication will be used in combination with Fludara (fludarabine) and cyclophosphamide

   If yes, **approve as follows by GPID or GPI-14 and enter two prior authorizations:**
   - **FIRST APPROVAL:**
     - **Approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials**
   - **SECOND APPROVAL (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**
     - **Approve 6 months of Arzerra 100mg/5mL with a quantity limit of #10 vials per 28 days (total fill count of 6) OR**
     - **Approve 6 months of Arzerra 1,000mg/50mL with a quantity limit of #1 vial per 28 days (total fill count of 6)**

   If no, continue to #4.

4. Is the request for extended treatment of chronic lymphocytic leukemia (CLL) and does the patient meet **ALL** of the following criteria?
   - The patient is in complete or partial response
   - The patient has received at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia (CLL)

   If yes, **approve as follows by GPID or GPI-14 and enter three prior authorizations:**
   - **FIRST APPROVAL:**
     - **Approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials**
   - **SECOND APPROVAL (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**
     - **Approve one fill of Arzerra 100mg/5mL with a quantity limit of #10 vials OR**
     - **Approve one fill of Arzerra 1,000mg/50mL with a quantity limit of #1 vial**
   - **THIRD APPROVAL (Please enter a start date of 7 WEEKS AFTER the start date of the second approval):**
     - **Approve 24 months of Arzerra 100mg/5mL with a quantity limit of #10 vials per 8 weeks (total fill count of 13) OR**
     - **Approve 24 months of Arzerra 1,000mg/50mL with a quantity limit of #1 vial per 8 weeks (total fill count of 13)**

   If no, continue to #5.

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OFATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Is the request for the treatment of refractory chronic lymphocytic leukemia (CLL) **AND** does the patient meet the following criterion?
   - The patient is refractory to Fludara (fludarabine) and Campath (alemtuzumab)

   If yes, **approve as follows by GPID or GPI-14 and enter three prior authorizations:**
   - **FIRST APPROVAL:**
     - **Approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials**
   - **SECOND APPROVAL (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**
     - **Approve 7 weeks of Arzerra 100mg/5mL with a quantity limit of #20 vials per 7 days (total fill count of 7) OR**
     - **Approve 7 weeks of Arzerra 1,000mg/50mL with a quantity limit of #2 vials per 7 days**
   - **THIRD APPROVAL (Please enter a start date of 4 WEEKS AFTER the end date of the second approval):**
     - **Approve 16 weeks of Arzerra 100mg/5mL with a quantity limit of #20 vials per 28 days (total fill count of 4) OR**
     - **Approve 16 weeks of Arzerra 1,000mg/50mL with a quantity limit of #2 vials per 28 days (total fill count of 4)**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OFATUMUMAB (Arzerra)** requires the following rule(s) be met for approval:
   A. You have chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer)
   B. If you have previously untreated chronic lymphocytic leukemia, approval also requires:
      1. You have not received previous treatment for chronic lymphocytic leukemia
      2. Fludara (fludarabine)-based therapy is considered inappropriate for you
      3. The requested medication will be used in combination with chlorambucil
   C. If you have relapsed chronic lymphocytic leukemia (type of blood and bone marrow cancer that has returned), approval also requires:
      1. The requested medication will be used in combination with Fludara (fludarabine) and cyclophosphamide
   (Denial text continued on next page)

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OFATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

D. If you are requesting extended treatment of chronic lymphocytic leukemia, approval also requires:
1. You are in complete or partial response
2. You have received at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia

E. If you have refractory chronic lymphocytic leukemia, approval also requires:
1. You are refractory (non-responsive) to Fludara (fludarabine) and Campath (alemtuzumab)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Arzerra.

REFERENCES
Arzerra [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. September 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 11/09
Client Approval: 03/21
P&T Approval: 11/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OFATUMUMAB-SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OFATUMUMAB	KESIMPTA		48513	GPI-10 (6240506500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for a total of 12 months by GPID or GPI-10 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #1.2mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #0.4mL per 28 days (Enter a start date of 3 weeks AFTER THE START DATE of the first approval).**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #0.4mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OFATUMUMAB-SQ (Kesimpta)** requires the following rules be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OFATUMUMAB-SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kesimpta.

REFERENCES

Kesimpta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024.

Created: 09/20
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLAPARIB	LYNPARZA	41642		GPI-10 (2153556000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to first-line platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - The patient's diagnosis is confirmed by an FDA-approved companion diagnostic for Lynparza

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation
   - The patient's cancer is associated with a homologous recombination deficiency (HRD)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability, AND Lynparza will be used in combination with bevacizumab

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation, as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient is in complete or partial response to platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - Lynparza will be used as monotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #4.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of high risk early breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - Lynparza will be used as adjuvant treatment
   - The patient's cancer is HER2-negative
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with neoadjuvant or adjuvant chemotherapy (e.g., doxorubicin, paclitaxel)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of metastatic breast cancer (ICD-10 C79.81; Group C50) and meet **ALL** of the following criteria?
   - The patient's cancer is HER2-negative
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with chemotherapy (e.g., doxorubicin, docetaxel) in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient does not have hormone receptor (HR)-positive breast cancer
   - The patient has a hormone receptor (HR)-positive breast cancer and has been treated with prior endocrine therapy or is considered inappropriate for endocrine therapy (e.g., tamoxifen, Arimidex [anastrozole])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have a diagnosis of metastatic pancreatic adenocarcinoma (ICD-10 Group C25) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #8.

8. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #9.
   If no, continue to #12.

9. Does the patient meet **BOTH** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has progressed following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa, Zytiga)

   If yes, continue to #11.
   If no, continue to #10.

10. Does the patient meet **BOTH** of the following criteria?
    - Lynparza will be used in combination with abiraterone (Yonsa, Zytiga) AND prednisone or prednisolone
    - The patient's cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

11. Does the patient meet **ONE** of the following criteria?
    - The patient had a bilateral orchiectomy
    - The patient has a castrate testosterone level (i.e., less than 50 ng/dL)
    - Lynparza will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

12. Is the request for a currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document? (see FDA website for approved drugs indications: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm)

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
    If no, do not approve.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **OLAPARIB (Lynparza)** requires the following rule(s) be met for approval:
    A. You have ONE of the following:
        1. Advanced or recurrent (returning) epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (types of reproductive system cancers)
        2. High risk early breast cancer
        3. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
        4. Metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
        5. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
        6. A currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document

    (Denial text continued on next page)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

B. If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
1. You are 18 years of age or older
2. You are in complete or partial response to first-line platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
3. Your diagnosis is confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
4. You meet ONE of the following:
   a. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation)
   b. Your cancer is associated with a homologous recombination deficiency (HRD: type of gene mutation)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation), AND Lynparza will be used in combination with bevacizumab

C. If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
1. You are 18 years of age or older
2. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
3. You are in complete or partial response to platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
4. Lynparza will be used as monotherapy (used alone)

D. If you have high risk early breast cancer, approval also requires:
1. Lynparza will be used as adjuvant (add-on) treatment
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
4. You have been treated with neoadjuvant or adjuvant chemotherapy (cancer treatment given before the main treatment or as add-on therapy such as doxorubicin, paclitaxel)

(Denial text continued on next page)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

E. If you have metastatic breast cancer, approval also requires:
1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
3. You have been treated with chemotherapy (such as doxorubicin, docetaxel) in the neoadjuvant (given before the main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
4. You meet ONE of the following:
   a. You do not have hormone receptor (HR)-positive breast cancer
   b. You have hormone receptor (HR)-positive breast cancer and have been treated with prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]), or endocrine therapy is considered inappropriate for you

F. If you have metastatic pancreatic adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
3. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (such as paclitaxel, docetaxel, cisplatin, carboplatin)

G. If you have metastatic castration-resistant prostate cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your cancer has worsened following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa or Zytiga) AND has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   b. Lynparza will be used in combination with abiraterone (Yonsa or Zytiga) and with prednisone or prednisolone AND your cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
3. You meet ONE of the following:
   a. You had a bilateral orchiectomy (both testicles have been surgically removed)
   b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
   c. Lynparza will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OLAPARIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lynparza.

REFERENCES

Lynparza tablets [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals; July 2025.

Created: 12/14
Effective: 02/09/26 Client Approval: 02/26 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLEZARSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLEZARSEN SODIUM	TRYNGOLZA	50111		GPI-10 (3090626530)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of familial chylomicronemia syndrome (FCS) (ICD-10 E78.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Tryngolza will be used as an adjunct therapy to diet
   - Tryngolza will NOT be used concurrently with another agent (e.g., Redemplo [plozasiran]) for the treatment of FCS

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient's FCS diagnosis been confirmed with **ONE** of the following criteria?
   - Genetic testing
   - History of fasting triglycerides of at least 1000 mg/dL on repeated testing (for at least 3 prior occasions) AND a history of recurrent acute pancreatitis that is not caused by alcohol or cholelithiasis, a history of hospitalization for severe abdominal pain without other explainable cause, or a family history of hypertriglyceridemia-induced pancreatitis

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.8mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of severe hypertriglyceridemia and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is adhering to or has previously tried guideline-recommended lifestyle interventions for triglyceride reduction, including dietary modifications and physical activity when clinically appropriate and feasible
   - The patient has a baseline fasting triglyceride level of at least 500 mg/dL
   - The patient had a trial of or contraindication to TWO clinical standard of care triglyceride lowering therapies (e.g., Vascepa [icosapent ethyl], Lovaza [omega-3 acid ethyl esters], Lopid [gemfibrozil], fenofibrate, statin [e.g., atorvastatin, simvastatin, rosuvastatin])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.8mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OLEZARSEN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT:

Our guideline named **OLEZARSEN (Tryngolza)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
   2. Severe hypertriglyceridemia (high levels of fat in the blood)

B. If you have familial chylomicronemia syndrome, approval also requires:
   1. You are 18 years of age or older
   2. You will use Tryngolza as an adjunct (add-on) therapy to diet
   3. You will NOT use Tryngolza concurrently (at the same time) with another medication (such as Redemplo [plozasiran]) for the treatment of familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
   4. Your familial chylomicronemia syndrome (FCS: a type of rare genetic condition) has been confirmed with ONE of the following:
      a. Genetic testing (a type of lab test)
      b. History of fasting triglycerides (a type of fat) of at least 1000 mg/dL on repeated testing (for at least 3 prior occasions) AND a history of recurrent acute pancreatitis (short-term inflammation of the pancreas) that is not caused by alcohol or cholelithiasis (hard, pebble-like stones that form inside gallbladder), a history of hospitalization for severe abdominal pain without other explainable cause, or a family history of hypertriglyceridemia-induced pancreatitis (high levels of fat in the blood due to pancreas inflammation)

C. If you have severe hypertriglyceridemia, approval also requires:
   1. You are 18 years of age or older
   2. You are adhering to (keeping up with) or have previously tried guideline-recommended lifestyle interventions for triglyceride (a type of fat) reduction (decrease), including dietary modifications (changes) and physical activity when clinically appropriate and feasible (doable)
   3. You have a baseline (before treatment) fasting triglyceride (a type of lab test) level of at least 500 mg/dL
   4. You have tried or have a contraindication to (harmful for you to use) TWO clinical standard of care triglyceride (a type of fat) lowering therapies (such as Vascepa [icosapent ethyl], Lovaza [omega-3 acid ethyl esters], Lopid [gemfibrozil], fenofibrate, statin [such as atorvastatin, simvastatin, rosuvastatin])

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OLEZARSEN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of familial chylomicronemia syndrome (FCS) (ICD-10 E78.3) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit as demonstrated by a reduction in triglyceride levels
   - Tryngolza will NOT be used concurrently with another agent (e.g., Redemplo [plozasiran]) for the treatment of FCS

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.8mL per 28 days.** If no, continue to #2.

2. Does the patient have a diagnosis of severe hypertriglyceridemia **AND** meet the following criterion?
   - The patient has experienced a clinical benefit as demonstrated by a reduction in triglyceride levels or acute pancreatitis events

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.8mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **OLEZARSEN (Tryngolza)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. You have familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
      2. Severe hypertriglyceridemia (high levels of fat in the blood)

   B. If you have familial chylomicronemia syndrome, renewal also requires:
      1. You have experienced a clinical benefit as shown by a reduction (decrease) in triglyceride (a type of fat) levels
      2. You will NOT use Tryngolza concurrently (at the same time) with another medication (such as Redemplo [plozasiran]) for the treatment of familial chylomicronemia syndrome (FCS: a type of rare genetic condition)

   C. If you have severe hypertriglyceridemia, renewal also requires:
      1. You have experienced a clinical benefit as shown by a reduction (decrease) in triglyceride (a type of fat) levels or acute pancreatitis (short-term inflammation of the pancreas) events

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OLEZARSEN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tryngolza.

REFERENCES

Tryngolza [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals Inc.; June 2026.

Created: 01/25
Effective: 08/28/26 Client Approval: 08/26 DMC Approval: 08/25/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLIPUDASE ALFA-RPCP (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLIPUDASE ALFA-RPCP	XENPOZYME	48267		GPI-10 (3090156030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acid sphingomyelinase deficiency (ASMD) and meet **ALL** of the following criteria?
   - The patient has non-central nervous system manifestations of ASMD
   - The patient has baseline alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels within 1 month of Xenpozyme initiation date

   If yes, **approve for lifetime by HICL or GPI-10 for 2 fills per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OLIPUDASE ALFA-RPCP (Xenpozyme)** requires the following rule(s) be met for approval:
   A. You have acid sphingomyelinase deficiency (ASMD: a type of rare genetic disorder that affects the body's ability to break down fat)
   B. You have non-central nervous system manifestations (affected organs are not in the brain or spinal cord) of ASMD
   C. You have baseline alanine aminotransferase (ALT: a type of liver enzyme test) and aspartate aminotransferase (AST: a type of liver enzyme test) levels within 1 month of Xenpozyme start date

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenpozyme.

REFERENCES

Xenpozyme [Prescribing Information]. Cambridge, MA: Genzyme, Corp., August 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 11/22
Client Approval:11/22
P&T Approval: 10/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLUTASIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLUTASIDENIB	REZLIDHIA	48490		GPI-10 (2153496000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) (ICD-10 C92.02, C92.00) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OLUTASIDENIB (Rezlidhia)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML: a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: a type of enzyme) mutation, as detected by a Food and Drug Administration (FDA)-approved test

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezlidhia.

REFERENCES

Rezlidhia [Prescribing Information]. Greenville, NC: Rigel Pharmaceuticals, Inc.; December 2022.

Created: 01/23
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMACETAXINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMACETAXINE MEPESUCCINATE	SYNRIBO	24243		GPI-10 (2170004010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic or accelerated phase chronic myeloid leukemia (CML) (ICD-10 Group C92.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a resistance or intolerance to at least TWO tyrosine kinase inhibitors (e.g., Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib], Bosulif [bosutinib], Iclusig [ponatinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMACETAXINE (Synribo)** requires the following rule(s) be met for approval:
   A. You have chronic or accelerated phase chronic myeloid leukemia (CML: a type of blood cell cancer)
   B. You are 18 years of age or older
   C. You had a resistance (medication does not work as well) or intolerance (side effect) to at least TWO tyrosine kinase inhibitors (such as Gleevec [imatinib], Sprycel [dasatinib], Tasigna [nilotinib], Bosulif [bosutinib], Iclusig [ponatinib])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Synribo.

REFERENCES

Synribo [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; May 2021.

Created: 12/12
Effective: 03/04/26 Client Approval: 03/26 P&T Approval: 05/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMADACYCLINE TOSYLATE	NUZYRA		45478	GPI-14 (04200050200320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) (ICD-10 J15.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's CABP infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*

   If yes, continue to #2.
   If no, continue to #6.

2. Is the request for continuation of care from an inpatient setting?

   If yes, **approve the 150 mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #30 per 14 days for 1 fill.**

   If no, continue to #3.

3. Is therapy prescribed by or in consultation with an infectious disease (ID) specialist?

   If yes, **approve the 150 mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #30 per 14 days for 1 fill.**

   If no, continue to #4.

4. Has an antimicrobial susceptibility test been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to at least TWO standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

   If yes, **approve the 150 mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #30 per 14 days for 1 fill.**

   If no, continue to #5.

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to at least TWO standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

   If yes, **approve the 150 mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #30 per 14 days for 1 fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of an acute bacterial skin or skin structure infection (ABSSSI) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's ABSSSI infection is caused by any of the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp.* (includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is therapy prescribed by or in consultation with an infectious disease (ID) specialist?

   If yes, **approve the 150 mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #30 per 14 days for 1 fill.**

   If no, continue to #8.

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

8. Has an antimicrobial susceptibility test been performed that meets **ALL** of the following criteria?
   - The results from the infection site culture indicate pathogenic organism(s) with resistance to at least TWO standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)
   - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

   If yes, **approve the 150 mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #30 per 14 days for 1 fill.**

   If no, continue to #9.

9. Does the patient meet **ALL** of the following criteria?
   - Antimicrobial susceptibility results are unavailable
   - The patient had a trial of or contraindication to at least TWO standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

   If yes, **approve the 150 mg tablet for 1 month by GPID or GPI-14 with a quantity limit of #30 per 14 days for 1 fill.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMADACYCLINE (Nuzyra)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Community-acquired bacterial pneumonia (CABP: a type of lung infection)
2. Acute bacterial skin or skin structure infection (ABSSSI: a type of skin condition)

B. If you have community-acquired bacterial pneumonia, approval also requires:

1. You are 18 years of age or older
2. Your infection is caused by any of the following susceptible microorganisms (bacteria that the medication can work on): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
3. You meet ONE of the following:
   a. Your request is for continuation of care from an inpatient setting (a healthcare facility where medical treatment is given overnight or longer)
   b. Therapy is prescribed by or in consultation with an infectious disease (ID) specialist (a doctor who specializes in the treatment of infections)
   c. Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
      i. The bacteria at the infection site culture is resistant (medication will not work on that bacteria) to at least TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
      ii. Nuzyra will work against the bacteria
   d. If an antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) at least TWO standard of care medications for community-acquired bacterial pneumonia (CABP: a type of lung infection) (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

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OMADACYCLINE

GUIDELINES FOR USE (CONTINUED)

C. If you have an acute bacterial skin or skin structure infection (ABSSSI), approval also requires:

1. You are 18 years of age or older
2. Your infection is caused by any of the following microorganisms (bacteria that the medication can work on): *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (*includes *S. anginosus, S. intermedius,* and *S. constellatus), Enterococcus faecalis, Enterobacter cloacae,* or *Klebsiella pneumoniae*
3. You meet ONE of the following:
   a. Therapy is prescribed by or in consultation with an infectious disease (ID) specialist (a doctor who specializes in the treatment of infections)
   b. Your antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) shows ALL of the following:
      i. The bacteria at the infection site culture is resistant (medication will not work on that bacteria) to at least TWO standard of care medications for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)
      ii. Nuzyra will work against the bacteria
   c. If an antimicrobial susceptibility test (lab test that shows what medications work on which bacteria) is not available, approval requires you have tried or have a contraindication to (harmful for you to use) at least TWO standard of care medications for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuzyra.

REFERENCES

Nuzyra [Prescribing Information]. Boston, MA: Paratek Pharmaceuticals, Inc.; March 2025.

Created: 03/19
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMALIZUMAB	XOLAIR	25399		GPI-10 (4460306000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate persistent asthma (ICD-10 Group J45.4) to severe persistent asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   - The patient has a positive skin prick or blood test (e.g., ELISA, FEIA) to a perennial aeroallergen
   - The patient has a baseline IgE serum level of at least 30 IU/mL
   - Xolair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

   If yes, **approve all formulations of the requested strength for 4 months by GPID or GPI-14 as follows:**
   - **150mg: #6 per 28 days.**
   - **75mg/0.5mL: #5mL per 28 days.**
   - **150mg/mL: #4mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, continue to #3.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve all formulations of the requested strength for 4 months by GPID or GPI-14 as follows:**
   - **150mg: #6 per 28 days.**
   - **75mg/0.5mL: #5mL per 28 days.**
   - **150mg/mL: #4mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease
   - The patient had a 56-day trial of ONE clinical standard of care agent: an intranasal corticosteroid (e.g., mometasone nasal spray)
   - Xolair will be used as add-on maintenance treatment
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, continue to #5.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of an IgE-mediated food allergy (ICD-10 Group Z91.01) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient will continue to avoid food allergens while on Xolair
   - The patient has an IgE serum level of at least 30 IU/mL
   - The patient has an allergen specific IgE serum level of at least 6 kUA/L to at least one food, OR a positive skin prick test to at least one food, OR a positive medically monitored food challenge to at least one food
   - Therapy is prescribed by or in consultation with an allergist or immunologist
   - The patient has an active prescription for epinephrine auto-injector/injection while on Xolair
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Palforzia) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of IgE-mediated food allergy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, continue to #6.

6. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient still experiences hives or angioedema on most days of the week for at least 6 weeks
   - The patient had a trial of and is maintained on, OR has a contraindication to, the clinical standard of care agent at four times the maximally labeled dose: a second generation H1 antihistamine (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

   If yes, **approve all formulations of the requested strength for 6 months by GPID or GPI-14 as follows:**
   - **150mg: #2 per 28 days.**
   - **150mg/mL: #2mL per 28 days.**
   - **300mg/2mL: #2mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. If you have moderate to severe persistent asthma, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   3. You have a positive skin prick or blood test, such as ELISA or FEIA (types of blood tests to identify allergies), to a perennial aeroallergen (airborne particles that cause allergies year-round)
   4. You have a baseline IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
   5. Xolair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long- acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   6. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

7. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

C. If you have chronic rhinosinusitis with nasal polyps, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
3. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
4. You have inadequately controlled disease
5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray)
6. Xolair will be used as add-on maintenance treatment (taken on a regular basis)
7. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

D. If you have an IgE-mediated food allergy, approval also requires:
1. You are 1 year of age or older
2. You will continue to avoid food allergens (not eating or coming into contact with food that causes an allergic reaction) while on Xolair
3. You have an IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
4. You have an allergen specific IgE serum level of at least 6 kUA/L to at least one food, OR a positive skin prick test (a type of allergy test) to at least one food, OR a positive medically monitored food challenge to at least one food
5. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
6. You have an active prescription for epinephrine auto-injector/injection while on Xolair
7. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy

E. If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
4. You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), the clinical standard of care medication at four times the maximally labeled dose: a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
5. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMALIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate persistent asthma (ICD-10 Group J45.4) to severe persistent asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   - **150mg: #6 per 28 days.**
   - **75mg/0.5mL: #5mL per 28 days.**
   - **150mg/mL: #4mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of an IgE-mediated food allergy (ICD-10 Group Z91.01) and meet **ALL** of the following criteria?
   - The patient has persistent IgE-mediated food allergy
   - The patient has an active prescription for epinephrine auto-injector/injection while on Xolair
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Palforzia) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of IgE-mediated food allergy

   If yes, **approve for 24 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient is maintained on, OR has a contraindication to, a second generation H1 anti-histamine (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
   - Xolair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 as follows:**
   - **150mg: #2 per 28 days.**
   - **150mg/mL: #2mL per 28 days.**
   - **300mg/2mL: #2mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. If you have moderate to severe persistent asthma, renewal also requires:
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]), or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Xolair)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in percent predicted FEV1 (type of lung test) from pre- treatment baseline (before starting Xolair)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. If you have chronic rhinosinusitis with nasal polyps, renewal also requires:
   1. You have shown a clinical benefit compared to baseline (before starting Xolair) (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

D. If you have an IgE-mediated food allergy, renewal also requires:
1. You have persistent IgE-mediated food allergy
2. You have an active prescription for epinephrine auto-injector/injection while on Xolair
3. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy

E. If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:
1. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
2. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
3. You will NOT use Xolair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolair.

REFERENCES
Xolair [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2024.

Created: 08/03
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB-IGEC

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMALIZUMAB-IGEC	OMLYCLO	50329		GPI-10 (4460306002)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate persistent asthma (ICD-10 Group J45.4) to severe persistent asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   - The patient has a positive skin prick or blood test (e.g., ELISA, FEIA) to a perennial aeroallergen
   - The patient has a baseline IgE serum level of at least 30 IU/mL
   - Omlyclo will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g., prednisone) burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or an emergency room visit within the past 12 months

   If yes, **approve for 4 months by GPID or GPI-14 for all of the following strengths:**
   - **75mg/0.5mL: #5mL per 28 days.**
   - **150mg/mL: #4mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, continue to #3.

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OMALIZUMAB-IGEC

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 4 months by GPID or GPI-14 for all of the following strengths:**
   - **75mg/0.5mL: #5mL per 28 days.**
   - **150mg/mL: #4mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease
   - The patient had a 56-day trial of ONE clinical standard of care agent: an intranasal corticosteroid (e.g., mometasone nasal spray)
   - Omlyclo will be used as add-on maintenance treatment
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8mL per 28 days.**
   If no, continue to #5.

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OMALIZUMAB-IGEC

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of an IgE-mediated food allergy (ICD-10 Group Z91.01) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient will continue to avoid food allergens while on Omlyclo
   - The patient has an IgE serum level of at least 30 IU/mL
   - The patient has an allergen specific IgE serum level of at least 6 kUA/L to at least one food, OR a positive skin prick test to at least one food, OR a positive medically monitored food challenge to at least one food
   - Therapy is prescribed by or in consultation with an allergist or immunologist
   - The patient has an active prescription for epinephrine auto-injector/injection while on Omlyclo
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Palforzia) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of IgE-mediated food allergy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 28 days.** If no, continue to #6.

6. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient still experiences hives or angioedema on most days of the week for at least 6 weeks
   - The patient had a trial of and is maintained on, OR has a contraindication to, the clinical standard of care agent at four times the maximally labeled dose: a second generation H1 antihistamine (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.** If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OMALIZUMAB-IGEC

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT:

Our guideline named **OMALIZUMAB-IGEC (Omlyclo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. If you have moderate to severe persistent asthma, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   3. You have a positive skin prick or blood test, such as ELISA or FEIA (types of blood tests to identify allergies), to a perennial aeroallergen (airborne particles that cause allergies year-round)
   4. You have a baseline IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
   5. Omlyclo will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   6. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma (a type of lung condition)

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OMALIZUMAB-IGEC

INITIAL CRITERIA (CONTINUED)

7. You meet ONE of the following:
   a. You have experienced at least ONE asthma (a type of lung condition) exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
   b. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
   c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

C. If you have chronic rhinosinusitis with nasal polyps, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
3. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
4. You have inadequately controlled disease
5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray)
6. Omlyclo will be used as add-on maintenance treatment (taken on a regular basis)
7. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps (inflammation of nasal and sinus ways with small growths in the nose)

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OMALIZUMAB-IGEC

INITIAL CRITERIA (CONTINUED)

D. If you have an IgE-mediated food allergy, approval also requires:
1. You are 1 year of age or older
2. You will continue to avoid food allergens (not eating or coming into contact with food that causes an allergic reaction) while on Omlyclo
3. You have an IgE (type of antibody that is produced by the immune system if there is an allergy) serum (blood) level of at least 30 IU/mL
4. You have an allergen specific IgE serum level of at least 6 kUA/L to at least one food, OR a positive skin prick test (a type of allergy test) to at least one food, OR a positive medically monitored food challenge to at least one food
5. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
6. You have an active prescription for epinephrine auto-injector/injection while on Omlyclo
7. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy (body's reaction to a food allergy)

E. If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks
4. You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), the clinical standard of care medication at four times the maximally labeled dose: a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
5. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria) (severe itching with unknown cause)

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OMALIZUMAB-IGEC

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate persistent asthma (ICD-10 Group J45.4) to severe persistent asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Tezspire [tezepelumab-ekko]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **75mg/0.5mL: #5mL per 28 days.**
   - **150mg/mL: #4mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OMALIZUMAB-IGEC

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8mL per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of an IgE-mediated food allergy (ICD-10 Group Z91.01) and meet **ALL** of the following criteria?
   - The patient has persistent IgE-mediated food allergy
   - The patient has an active prescription for epinephrine auto-injector/injection while on Omlyclo
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Palforzia) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of IgE-mediated food allergy

   If yes, **approve for 24 months by HICL or GPI-10 with a quantity limit of #8mL per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient is maintained on, OR has a contraindication to, a second generation H1 anti-histamine (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
   - Omlyclo will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OMALIZUMAB-IGEC

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT:

Our guideline named **OMALIZUMAB-IGEC (Omlyclo)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)
   3. IgE-mediated food allergy (body's reaction to a food allergy)
   4. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. If you have moderate to severe persistent asthma, renewal also requires:
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
   2. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Tezspire [tezepelumab-ekko]), or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma (a type of lung condition)
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma (a type of lung condition) exacerbations (worsening of symptoms) from baseline (before starting Omlyclo)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in percent predicted FEV1 (type of lung test) from pre- treatment baseline (before starting Omlyclo)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. If you have chronic rhinosinusitis with nasal polyps, renewal also requires:
   1. You have shown a clinical benefit compared to baseline (before starting Omlyclo) (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps (inflammation of nasal and sinus ways with small growths in the nose)

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OMALIZUMAB-IGEC

RENEWAL CRITERIA (CONTINUED)

D. If you have an IgE-mediated food allergy, renewal also requires:
1. You have persistent IgE-mediated food allergy (body's reaction to a food allergy)
2. You have an active prescription for epinephrine auto-injector/injection while on Omlyclo
3. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Palforzia) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of IgE-mediated food allergy (body's reaction to a food allergy)

E. If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:
1. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
2. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
3. You will NOT use Omlyclo concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria) (severe itching with unknown cause)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Omlyclo and Xolair.

REFERENCES

Omlyclo [Prescribing Information]. Jersey City, NJ: Celltrion USA, Inc.; December 2025.
Xolair [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2026.

Created: 08/26
Effective: 08/22/26 DMC Approval: 8/18/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMAVELOXOLONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMAVELOXOLONE	SKYCLARYS	48741		GPI-10 (7413506000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Friedreich's ataxia (ICD-10 G11.11) and meet **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient's diagnosis is confirmed by genetic testing (homozygous for GAA repeat expansion in intron-1 of FXN gene)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMAVELOXOLONE (Skyclarys)** requires the following rule(s) be met for approval:
   A. You have Friedreich's ataxia (a type of nervous system and movement disorder)
   B. You are 16 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   D. Your diagnosis is confirmed by genetic testing (homozygous for guanine-adenine-adenine [GAA] repeat expansion in intron-1 of frataxin [FXN] gene) (a type of gene mutation)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMAVELOXOLONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Friedreich's ataxia (ICD-10 G11.11)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMAVELOXOLONE (Skyclarys)** requires the following rule(s) be met for renewal:
   A. You have Friedreich's ataxia (a type of nervous system and movement disorder)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyclarys.

REFERENCES

Skyclarys [Prescribing Information]. Cambridge, MA: Biogen U.S. Corporation; December 2024.

Created: 04/23
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMEPRAZOLE-SODIUM BICARBONATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMEPRAZOLE/ SODIUM BICARBONATE	KONVOMEP		52842	GPI-14 (49996002601920)	
	ZEGERID, OMEPRAZOLE-SODIUM BICARBONATE		26634 24144	GPI-14 (49996002603020, 49996002603040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient 1 month to 11 years of age?

   If yes, continue to #3.
   If no, continue to #2.

2. Is the patient 12 years of age or older **AND** meet the following criterion?
   - The patient has a contraindication to OR is unable to swallow the tablet/capsule formulation of omeprazole, pantoprazole, esomeprazole, or lansoprazole

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient had a trial of or contraindication to the preferred agent: generic esomeprazole packets?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OMEPRAZOLE-SODIUM BICARBONATE

INITIAL CRITERIA (CONTINUED)

4. Is the request for H. Pylori eradication?

If yes, **approve the requested medication for 1 month by GPID or GPI-14 as follows:**
- **Konvomep 2-84mg/mL: #10mL per day.**
- **Zegerid (omeprazole-sodium bicarbonate) 20-1680mg: #1 per day.**
- **Zegerid (omeprazole-sodium bicarbonate) 40-1680mg: #1 per day.**

If no, **approve the requested medication for 12 months by GPID or GPI-14 as follows:**
- **Konvomep 2-84mg/mL: #10mL per day.**
- **Zegerid (omeprazole-sodium bicarbonate) 20-1680mg: #1 per day.**
- **Zegerid (omeprazole-sodium bicarbonate) 40-1680mg: #1 per day.**

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMEPRAZOLE-SODIUM BICARBONATE (Konvomep, Zegerid)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. **If you are 1 month to 11 years of age, approval also requires:**
      a. You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic esomeprazole packets
   2. **If you are 12 years of age or older, approval also requires:**
      a. You have a contraindication to (harmful for you to use) OR you are unable to swallow the tablet/capsule formulation of omeprazole, pantoprazole, esomeprazole, or lansoprazole
      b. You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic esomeprazole packets

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMEPRAZOLE-SODIUM BICARBONATE

RENEWAL CRITERIA

NOTE: For the diagnosis of H. pylori eradication, please refer to the Initial Criteria section.

1. Does the patient meet **ALL** of the following criteria?
   - The patient has had clinical benefit
   - The patient requires continued therapy of the requested medication

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 as follows:**
   - **Konvomep 2-84mg/mL: #10mL per day.**
   - **Zegerid (omeprazole-sodium bicarbonate) 20-1680mg: #1 per day.**
   - **Zegerid (omeprazole-sodium bicarbonate) 40-1680mg: #1 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMEPRAZOLE-SODIUM BICARBONATE (Konvomep, Zegerid)** requires the following rule(s) be met for renewal:
   A. You have had clinical benefit (medication worked)
   B. You require continued therapy of the requested medication

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Konvomep and Zegerid.

REFERENCES

Konvomep [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; April 2024.
Zegerid [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; July 2023.

Created: 05/25
Effective: 03/04/26 Client Approval: 03/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMIDUBICEL-ONLV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMIDUBICEL-ONLV	OMISIRGE	48861		GPI-10 (2165085010)	

GUIDELINES FOR USE

1. Is the request to reduce the time to neutrophil recovery and the incidence of infection in a patient with a hematologic malignancy and the patient meets **ALL** of the following criteria?
   - The patient will be undergoing umbilical cord blood transplantation following myeloablative conditioning (e.g., chemotherapy, radiation)
   - The patient is 12 years of age or older

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill.**
   If no, continue to #2.

2. Does the patient have a diagnosis of severe aplastic anemia (SAA) (ICD-10 D61.9) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Omisirge will be used following reduced intensity conditioning

   If yes, **approve for 30 days by HICL or GPI-10 for 1 fill.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OMIDUBICEL-ONLV (Omisirge)** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. To reduce the time to neutrophil recovery (lab levels normalize) and the rate of infection and you have a hematologic malignancy (cancer that affects the blood, bone marrow, and lymph nodes)
      2. Severe aplastic anemia (SAA: a type of blood disorder)

   B. If the request is to reduce the time to neutrophil recovery and the rate of infection, and you have a hematologic malignancy, approval also requires:
      1. You will be undergoing umbilical cord blood transplantation (type of procedure) following myeloablative conditioning (a type of treatment such as chemotherapy, radiation)
      2. You are 12 years of age or older

   C. If you have severe aplastic anemia, approval also requires:
      1. You are 6 years of age or older
      2. Omisirge will be used after reduced intensity conditioning (a type of treatment to lower the risk of complications)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMIDUBICEL-ONLV

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Omisirge.

REFERENCES
Omisirge [Prescribing Information]. Jerusalem, Israel: Gamida Cell Ltd.; December 2025.

Created: 08/23
Effective: 01/12/26 Client Approval: 12/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ONABOTULINUM TOXIN A

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ONABOTULINUMTOXINA	BOTOX	04867		GPI-10 (7440002005)	BRAND ≠ BOTOX COSMETIC

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines) (ICD-10 L98.8; Group L81)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines (greater than or equal to 15 days per month with headaches lasting 4 hours a day or longer) (ICD-10 Groups G43.7, G43.E) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Botox is prescribed for the prophylaxis of headaches
   - The patient had a trial of TWO of the following prophylactic migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, metoprolol

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of overactive bladder (OAB) (ICD-10 N32.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to an anticholinergic medication (e.g., oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, Sanctura)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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ONABOTULINUM TOXIN A

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of urinary incontinence (ICD-10 R32) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury [SCI], multiple sclerosis [MS])
   - The patient had a trial of or contraindication to an anticholinergic medication (e.g., oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, Sanctura)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of neurogenic detrusor overactivity (NDO) and meet **ALL** of the following criteria?
   - The patient is 5 years of age or older
   - The patient had an inadequate response to or is intolerant of anticholinergic medications (e.g., oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, Sanctura)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have a diagnosis of spasticity (ICD-10 Group G81.1; G04.1, G11.4, G80.0, G80.1, G80.2) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Does the patient have a diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) (ICD-10 G24.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO preferred agents: Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

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ONABOTULINUM TOXIN A

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of severe axillary hyperhidrosis (excessive underarm sweating) (ICD-10 L74.510) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

9. Does the patient have a diagnosis of blepharospasm (involuntary forcible closure of the eyelid) (ICD-10 G24.5) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #10.

10. Does the patient have a diagnosis of strabismus (crossed eyes) (ICD-10 H50.9) **AND** meet the following criterion?
    - The patient is 12 years of age or older

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **ONABOTULINUM TOXIN A (Botox)** requires the following rule(s) be met for approval:
    A. You have ONE of the following:
       1. Chronic migraine headaches (at least 15 days per month with headaches lasting 4 hours a day or longer)
       2. Overactive bladder (a type of bladder condition)
       3. Urinary incontinence (loss of bladder control)
       4. Neurogenic detrusor overactivity (a type of bladder condition)
       5. Spasticity (stiffness or tightness of your muscles)
       6. Cervical dystonia (a type of muscle condition)
       7. Severe axillary hyperhidrosis (excessive underarm sweating)
       8. Blepharospasm (a type of eye disease)
       9. Strabismus (a type of eye condition)

    (Initial denial text continued on next page)

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ONABOTULINUM TOXIN A

INITIAL CRITERIA (CONTINUED)

B. If you have chronic migraine headaches (at least 15 days per month with headaches lasting 4 hours a day or longer), approval also requires:
1. You are 18 years of age or older
2. Botox is prescribed for the prophylaxis (prevention) of headaches
3. You have tried TWO of the following migraine (a type of headache) prevention treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, metoprolol

C. If you have overactive bladder, approval also requires:
1. You are 18 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) an anticholinergic medication (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, Sanctura)

D. If you have urinary incontinence, approval also requires:
1. You are 18 years of age or older
2. You have detrusor (bladder muscle) overactivity associated with a neurologic (nervous system) condition (such as a spinal cord injury [SCI], multiple sclerosis [MS: a type of nerve disorder])
3. You have tried or have a contraindication to (harmful for you to use) an anticholinergic medication (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, Sanctura)

E. If you have neurogenic detrusor overactivity, approval also requires:
1. You are 5 years of age or older
2. You did not have an adequate response (medication did not work) or you are not able to take anticholinergic medications (such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, VESIcare, Sanctura)

F. If you have spasticity, approval also requires:
1. You are 2 years of age or older

G. If you have cervical dystonia, approval also requires:
1. You are 18 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) TWO preferred medications: Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

H. If you have severe axillary hyperhidrosis, approval also requires:
1. You are 18 years of age or older

I. If you have blepharospasm, approval also requires:
1. You are 12 years of age or older

J. If you have strabismus, approval also requires:
1. You are 12 years of age or older

(Initial denial text continued on next page)

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ONABOTULINUM TOXIN A

INITIAL CRITERIA (CONTINUED)

NOTE: This medication will not be approved for a cosmetic indication (for example wrinkles - glabellar [between the eyebrows] lines, lateral canthal [outer corner of the eyes] lines, forehead lines).

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ONABOTULINUM TOXIN A

RENEWAL CRITERIA

NOTE: For diagnoses other than migraines, please refer to the Initial Criteria section.

1. Is the request for a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines) (ICD-10 L98.8; Group L81)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines (greater than or equal to 15 days per month with headaches lasting 4 hours a day or longer) (ICD-10 Group G43.7 and G43.E)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Has the patient experienced **ONE** of the following criteria?
   - A reduction in migraine or headache frequency of at least 2 days per month
   - A reduction in migraine severity
   - A reduction in migraine duration

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ONABOTULINUM TOXIN A

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the text you need to use does not already have definition(s) in it.

Our guideline named **ONABOTULINUM TOXIN A (Botox)** requires the following rule(s) be met for renewal:

A. You have chronic migraine headaches (at least 15 days per month with headaches lasting 4 hours a day or longer)
B. You have experienced ONE of the following:
   1. A reduction in migraine (a type of headache) or headache frequency of at least 2 days per month
   2. A reduction in migraine (a type of headache) severity
   3. A reduction in migraine (a type of headache) duration (length)

NOTE: This medication will not be approved for a cosmetic indication (such as wrinkles - glabellar lines [between the eyebrows], lateral canthal [outer corner of eye] lines, forehead lines).

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Botox.

REFERENCES

Botox [Prescribing Information]. Madison, NJ: Allergan, Inc.; August 2023.

Created: 10/22
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPICAPONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OPICAPONE	ONGENTYS	45536		GPI-10 (7315306000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease (ICD-10 Group G20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is experiencing “OFF” episodes
   - The patient will also be treated with carbidopa/levodopa (e.g., Sinemet, Sinemet CR, Parcopa)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient had a trial of, failure of, or contraindication to **TWO** Parkinson's disease agents from TWO different classes of the following?
   - Dopamine agonist (e.g., ropinirole, pramipexole, rotigotine)
   - Monoamine oxidase-inhibitors (MAO-I) (e.g., selegiline, rasagiline)
   - Adenosine receptor antagonist A2A (e.g., istradefylline)
   - Catechol-O-methyltransferase (COMT) inhibitors (e.g., entacapone, tolcapone)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPICAPONE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPICAPONE (Ongentys)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (PD: a type of movement disorder)
B. You are 18 years of age or older
C. You are experiencing 'OFF' episodes (period of symptoms in between doses)
D. You will also be treated with carbidopa/levodopa (such as Sinemet, Sinemet Controlled Release [CR], Parcopa)
E. You have tried, failed, or have a contraindication to (harmful for you to use) TWO Parkinson's disease medications from TWO different classes of medications:
    1. Dopamine agonist (such as ropinirole, pramipexole, rotigotine)
    2. Monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline)
    3. Adenosine receptor antagonist A2A (such as istradefylline)
    4. Catechol-O-methyltransferase (COMT) inhibitors (such as entacapone, tolcapone)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ongentys.

REFERENCES

Ongentys [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2020.

Created: 09/20
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID CUMULATIVE DOSING OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the soft-stop threshold or hard-stop threshold as noted in the POS reject messaging?

   NOTE: Claims should stop for DUR_MAX_CUMUL_DOSE 2 edit with Soft_DENY_LIMIT= X or HARD_DENY_LIMIT= X (i.e., Cumulative morphine milligram equivalent of [patient's current MME] = / exceeds threshold of [**soft-stop threshold**-mg MME or **hard-stop threshold**-mg MME]).

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve as follows:**
   - **Approval duration should be for 12 months by HICL or GPI-10.**
   - **NOTE: Please enter a class override to override the MME cumulative dosing for the duration of 12 months.**
   - **If the claim rejects after analyzing, then follow the clinical coverage determination process.**

   If no, continue to #3.

3. Is the prescriber aware of multiple prescribers for opioid prescriptions?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

4. Have **TWO** of the following criteria been met?
   - The patient's current level of opioid utilization is necessary and required for the level of pain management needed
   - The patient has been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
   - The patient has a pain contract in place
   - The patient does NOT have a history of substance abuse or addiction
   - The prescriber has committed to monitoring the state's Prescription Monitoring Program to ensure the controlled substance history is consistent with the prescribing record

   If yes, **approve as follows:**
   - **Approval duration should be for 12 months by HICL or GPI-10.**
   - **NOTE: Please enter a class override to override the MME cumulative dosing for the duration of 12 months.**
   - **If the claim rejects after analyzing, then follow the clinical coverage determination process.**

   If no, do not approve.
   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
   While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the amount of opiates prescribed and because your opiate amount exceeds or is equal to **[enter soft stop threshold]**-mg morphine milligram equivalent (MME) or **[enter hard stop threshold]**-mg morphine milligram equivalent (MME).
   [Proceed to enter Denial Text below]

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

A claim for a pain medication will be denied when there are two or more providers prescribing opioid medications for a patient who is receiving a high quantity of these agents. Our guideline named **OPIOID CUMULATIVE DOSING OVERRIDE** will allow you to receive a higher quantity of an opioid medication if ONE of the following rules (A or B) is met:

A. You have ONE of the following conditions:
   1. You are receiving palliative care (treatment for comfort from symptoms) or end-of life care
   2. You are enrolled in a hospice (end of life care)
   3. You are a resident of a long-term care facility or intermediate care for intellectually disabled
   4. You have sickle cell disease (a type of blood disorder)
   5. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

B. Your prescriber is aware that there is more than one provider prescribing opiates for you, AND you meet **TWO** of the following:
   1. Your current level of opioid use is necessary and required for your level of pain management needed
   2. You have been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
   3. You have a pain contract in place
   4. You do NOT have a history of substance abuse or addiction
   5. Your prescriber has committed to monitoring the state's Prescription Monitoring Program to make sure your controlled substance history is consistent with prescribing record

This safety edit allows for an override for an opioid product equal to or exceeding the **[enter soft stop threshold]**-mg morphine milligram equivalent (MME) or **[enter hard stop threshold]**-mg morphine milligram equivalent (MME). Please consult your physician if you have any questions about this safety edit on prescription opioid medications and the requirements needed for you to obtain an approval for higher quantities of these agents.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.
(Denial text continued on next page)

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT: Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter.
Prior authorization will be required for opioid prescriptions in excess of hard opioid edit. Soft opioid edit thresholds may be overridden by a dispensing pharmacist or provider/patient may request a coverage determination. This requirement should not apply to patients with, in hospice, those receiving palliative or end of life care, residents of a long-term facility, patients approved by case management or retrospective DUR Programming or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. Additional payment determination is required for patients identified as hospice. Soft-thresholds may also be overriden by the pharmacy via DUR PPS codes or as part of coverage determination process and by certain PPS codes. Hard-thresholds are overridable as part of the coverage determination process. The cumulative opioid edit minimizes false positives by accounting for known exceptions: 1) patients on hospice, have certain cancer diagnosis 2) overlapping dispensing dates for Rx refills and new Rx orders for continuing fills 3) high-dose opioid usage previously determined to be medically necessary (approved PAs, previous coverage determinations, case management) 4) no consecutive high-MME days' criterion as it would not prevent beneficiaries from reaching high opioid doses.

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OPIOID CUMULATIVE DOSING OVERRIDE

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID LONG-ACTING DUPLICATIVE THERAPY

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-1045: THERAPEUTIC DUPLICATION DENIAL (DRUG_TD)**
     (The incoming claim for a long-acting (LA) opioid will reject when the patient is concurrently taking a different long-acting opioid [different HICL] from a different prescriber.)

     If yes, continue to #2.
     If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

     If yes, **approve for 12 months by HICL or GPI-10 and set DRUG_TD_OVR to 'Y' for Yes.**
     If no, continue to #3.

3. Is the prescriber aware that the patient is concurrently receiving more than one long-acting opioid therapy?

     If yes, **approve for 12 months by HICL or GPI-10 and set DRUG_TD_OVR to 'Y' for Yes.**
     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID LONG-ACTING DUPLICATIVE THERAPY

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of two long-acting opioid drugs together that are from different prescribers. **[Proceed to enter Denial Text below]**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID LONG ACTING DUPLICATIVE THERAPY** allows approval of the requested drug taken together with other long-acting opioid drug(s) from different prescribers when ONE of the following conditions are met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that they are aware that you are concurrently receiving more than one long-acting opioid medication
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription medication and the requirements needed for you to obtain an approval for this agent.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT:
Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed**.**

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OPIOID LONG-ACTING DUPLICATIVE THERAPY

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
"…we expect all Part D plan sponsors to implement a soft POS safety edit (which can be overridden by the pharmacist) for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion." *CMS 2019 Call Letter, page 252*
Prior authorization will be required for Long Acting (LA) opioid prescriptions when an incoming claim for a long-acting opioid overlaps with another a long acting opioid (different HICL) claim(s) from a different prescriber(s). The edit can be overridden by professional pharmacy professional service (PPS) code at POS or by a PA. This requirement does not apply to patients receiving palliative care or end-of-life care, those enrolled in hospice, patients that are a resident of a long-term care facility or intermediate care for intellectually disabled, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. This guideline also allows an override when there is physician attestation that the prescriber is aware that the patient is concurrently receiving long acting duplicative therapy and would like to proceed with treatment for a clinically appropriate indication.

REFERENCES

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID NAIVE FILL LIMIT

Generic	Brand	HICL	GCN	Medi-Span	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   REJ-306-1066: THIS CLAIM EXCEEDS LIMIT OF 2 OPIOID FILLS IN 30 DAYS

   [**NOTE**: The incoming opioid analgesic claim will reject if an initially opioid-naive member exceeds two opioid fills regardless of day supply, for the same drug (HICL), within the past 30 days. In addition, the patient is considered opioid-naive if they have no history of an opioid analgesic drug(s) in the past 60 days (not counting same day claims).]

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set FILL_LIMIT_OVR to 'Y' for Yes.**
   If no, continue to #3.

3. Has the prescriber indicated that the additional fill of the requested opioid analgesic medication is intended and clinically appropriate for the patient?

   [NOTE: Refer to the Medical Request Form (MRF) or chart notes if provided (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, **approve for 1 month, for one fill count by HICL or GPI-10 and set FILL_LIMIT_OVR to 'Y' for Yes.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID NAIVE FILL LIMIT

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
[NOTE: Enter proactive PAs for other UM overrides not including the Opioid Naive Fill Limit, if applicable.]

While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because you exceeded the fill limit of the requested opioid analgesic.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID NAIVE FILL LIMIT** allows an approval of the requested drug when it exceeds the fill limit for an initially opioid-naïve patient (those who have not used opioid drugs within the past 60 days) when ONE of the following conditions is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that the additional fill of the requested opioid medication is intended and clinically appropriate for you
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPIOID NAIVE FILL LIMIT

RATIONALE

To ensure appropriate use of opioids and to address prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.

In addition, the goal is to align with the opioid restrictions from the SUPPORT Act. The SUPPORT Act is an acronym for the Congress HR 6 - *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.* The rule identified six requirements that each State and Managed Care Entity must have in place by October 1, 2019. CMS defined the SUPPORT Act requirements as minimum Drug Utilization Review (DUR) standards for MMCPs and they are listed below:

Safety edits, as specified by the states, for subsequent opioid fills and maximum daily morphine milligram equivalent that exceed state-defined limitations

Automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics

Monitoring antipsychotic prescribing for children

Process that identifies potential fraud or abuse by enrolled individuals and pharmacies

Report to the Secretary annually on state DUR activities

Have in place managed care contracts that include these provisions

The guideline also allows an override for patients with one of the following conditions:

Receiving palliative care or end-of-life care

Enrolled in hospice

Resident of a long-term care facility or intermediate care for intellectually disabled

Diagnosis of sickle cell disease

Being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

CMS noted that minimum standards may be expanded by the states or CMS in future rule making.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
OPIOIDS	OPIOIDS	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the soft-stop threshold hard-stop threshold as noted in the POS reject messaging?

   NOTE: Claims should stop for DUR_MAX_SINGLE_DOSE edit with Soft_DENY_LIMIT = X or HARD_DENY_LIMIT = X (i.e., morphine milligram equivalent of [patient's current MME] = / exceeds threshold of [**soft-stop threshold**-mg MME or **hard-stop threshold**-mg MME]).

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for an opioid product less than or equal to the hard-stop threshold-1 MME?

   If yes, **approve 12 months by HICL or GPI-10 up to hard-stop threshold-1 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

   If no, continue to #3.

3. Does the patient meet **ANY** of the following criteria?
   - The patient is receiving palliative care (ICD-10 Z51.5)
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is enrolled in hospice
   - The prescriber is a pain management specialist
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve 12 months by HICL or GPI-10. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

   If no, continue to #4.

4. Has the physician provided attestation that the requested high dose is considered medically necessary?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

GUIDELINES FOR USE (CONTINUED)

5. Is the request for an opioid with an MME equal to or exceeding the hard-stop threshold and the prescriber has not indicated an opioid MME threshold value?

   If yes, **approve for 12 months by HICL or GPI-10 up to 25% greater than the previously approved MME via the patient's claim profile or physician attestation, up to 300 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

   If no, continue to #6.

6. Did the physician indicate a maximum opioid threshold for the requested drug that is less than 300 MME?

   If yes, **approve for 12 months by HICL or GPI-10 as requested up to 300 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

   If no, continue to #7**.**

7. Is the request for an opioid with an MME equal to or exceeding the maximum threshold (300 MME) for a patient who is currently stable on this MME?

   If yes, **approve for 3 months by HICL or GPI-10. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**
   APROVAL TEXT: While your prior authorization for (enter requested drug) has been granted, your opiate amount is equal to or exceeds [300 morphine milligram equivalent (MME)] and is considered a high dose of opiate. Please consult with your pain management specialist regarding your treatment options.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPIOID SINGLE CLAIM DOSING AT POS** allows for an override of an opioid product equal to or exceeding the soft-stop threshold of **[enter soft stop threshold]**-mg morphine milligram equivalent (MME) at the pharmacy or by a prior authorization. The hard-stop threshold of **[enter hard stop threshold]**-mg morphine milligram equivalent (MME) is not overridable and requires a prior authorization.
   (Denial text continued on next page)

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OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

GUIDELINES FOR USE (CONTINUED)

An override will be provided if ONE (A or B) of the following rule(s) are met:

A. You meet ONE of the following conditions:
   1. You are receiving treatment for palliative care (treatment for comfort from symptoms)
   2. You have sickle cell disease (a type of blood disorder)
   3. You are enrolled in a hospice (end of life care)
   4. Your doctor is a pain management specialist
   5. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

B. Your physician confirms that the requested high dose is considered medically necessary.
   1. If the requested dose is lower than 300 MME, your prescriber must provide a maximum opioid threshold. If your prescriber does not provide a maximum threshold and the request is for an opioid with an MME equal to or exceeding **[enter hard-stop threshold]**-mg morphine milligram equivalent (MME), the claim will be approved up to 25 percent greater than the previously approved MME.
   2. If the requested dose is equal to or greater than 300 MME, approval will be granted if you are stable on the dose.

Please consult your pain management specialist regarding your treatment options.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

To align with opioid restrictions required by several states and to prevent overutilization of opioids and increase safety.

This advanced POS intervention blocks an incoming claim when a single claim's Morphine Milligram Equivalent (MME) is equal to or exceeds a specified hard-stop threshold (e.g. over 90 MME). The hard-stop is non-overridable except via prior authorization. The edit allows a soft stop on an incoming claim with an MME equal to or over a lower threshold (e.g. over 50 MME) that can be overridden by Pharmacy Professional Service (PPS) codes at the point-of-sale (POS) or by prior authorization. Overriding the hard threshold for OSCDP will also override the OSCDP soft threshold, but does not affect Opioid Cumulative Dosing Program (OCDP).

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OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

RATIONALE (CONTINUED)

This requirement does not apply to patients with sickle cell disease, patients in palliative care, hospice patients, patients with a prescription from a pain management specialist, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-ANTIPSYCHOTIC CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ- 433-1205: OPIOID-ANTIPSYCHOTIC CONFLICT FOUND (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_PSY'.**
   If no, continue to #3.

3. Has the prescriber indicated that the concurrent use of an opioid and an antipsychotic medication is intended and clinically appropriate for the patient?
   [NOTE: Refer to the Medical Request Form (MRF) or chart notes if provided (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_PSY'.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-ANTIPSYCHOTIC CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
[NOTE: Enter proactive PAs for other UM overrides not including the Opioid-Antipsychotic Concurrent Use, if applicable.]
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and an antipsychotic drug together.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-ANTIPSYCHOTIC CONCURRENT USE** allows an approval for use of an opioid with an antipsychotic medication (type of mental health drug) together when one of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that the use of an opioid and an antipsychotic medication together is intended and clinically appropriate for you
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPIOID-ANTIPSYCHOTIC CONCURRENT USE

RATIONALE

To mitigate the risk of overdose from dangerous combinations of antipsychotics and opioids while preserving patient access to drug regimens if deemed medically necessary.

In addition, align with the opioid restrictions from the SUPPORT Act. The SUPPORT Act is an acronym for the Congress HR 6 - *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.* The rule identified six requirements that each State and Managed Care Entity must have in place by October 1, 2019. CMS defined the SUPPORT Act requirements as minimum Drug Utilization Review (DUR) standards for MMCPs and are listed below:

Safety edits, as specified by the states, for subsequent opioid fills and maximum daily morphine milligram equivalent that exceed state-defined limitations

Automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics

Monitoring antipsychotic prescribing for children

Process that identifies potential fraud or abuse by enrolled individuals and pharmacies

Report to the Secretary annually on state DUR activities

Have in place managed care contracts that include these provisions

The guideline also allows an override for patients with one of the following conditions:

Receiving palliative care or end-of-life care

Enrolled in hospice

Resident of a long-term care facility or intermediate care for intellectually disabled

Diagnosis of sickle cell disease

Being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

CMS noted that minimum standards may be expanded by the states or CMS in future rule making.

REFERENCES

SUPPORT for Patients and Communities Act, H.R. 6, Section 1004, 115th Congress. (2018). Available at: https://www.congress.gov/bill/115th-congress/house-bill/6 . [Accessed 7/30/19].

CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary- level-opioid-point-sale-safety-edits-july-5-2024.pdf

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-BENZODIAZEPINE CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ- 433-1201: CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BZD'.**
   If no, continue to #3.

3. Has the prescriber provided attestation to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication?

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_BZD'.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-BENZODIAZEPINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and a benzodiazepine drug together.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval of use of an opioid with a benzodiazepine together when ONE of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor agrees to proceed with the concurrent use (at the same time) of an opioid and a benzodiazepine for a clinically appropriate indication (reason)
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.
(*Denial text continued on next* page)

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OPIOID-BENZODIAZEPINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT:
Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed**.**

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
"We expect that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019."*CMS 2019 Call Letter, page 251*
The claim will deny when there is concurrent use of benzodiazepines and opioids with any overlap in day supply. This can be overridden at POS or by a Prior Authorization. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.
This guideline allows an approval for patients with one of the following conditions:
Receiving palliative care or end-of-life care
Enrolled in hospice
Resident of a long-term care facility or intermediate care for intellectually disabled
Diagnosis of sickle cell disease
Physician attestation that the prescriber is aware that the patient is concurrently receiving a benzodiazepine with an opioid(s) and would like to proceed with an opioid and benzodiazepine
Being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

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OPIOID-BENZODIAZEPINE CONCURRENT USE

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-BUPRENORPHINE CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with **ONE** of the following error codes?
   - **REJ-433-1200 (DUR CONCURRENT USE): CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY**
   - **REJ-1064 (DUR_DD_DENY): DRUG-DRUG INTERACTION FOUND**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 with ONE of the following overrides:**
   - **For DUR_CONCURRENT_ USE Rejection: Set DUR_CONCURRENT_ OVR to 'OP_BUP'**
   - **For DUR_DD_DENY Rejection: Set OVR_RES to 'Y'**

   If the claim analysis continues to reject, follow the clinical coverage determination process.

   If no, continue to #3.

3. Has the prescriber provided attestation that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and needs to resume chronic opioid treatment? (**NOTE:** Consultation with an addiction medicine specialist is recommended)

   If yes, **approve for 4 months by HICL or GPI-10 with ONE of the following overrides:**
   - **For DUR_CONCURRENT_ USE Rejection: Set DUR_CONCURRENT_ OVR to 'OP_BUP'**
   - **For DUR_DD_DENY Rejection: Set OVR_RES to 'Y'**

   If the claim analysis continues to reject, follow the clinical coverage determination process.

   If no, continue to #4.

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OPIOID-BUPRENORPHINE CONCURRENT USE

GUIDELINES FOR USE

4. Is the prescriber aware that the patient is currently receiving buprenorphine or buprenorphine-containing agents for treatment of opioid dependency and has provided attestation to proceed with opioid treatment for an acute, clinically appropriate indication? (**NOTE:** Consultation with an addiction medicine specialist is recommended)

   If yes, **approve for 30 days by HICL or GPI-10 with ONE of the following overrides:**
   - **For DUR_CONCURRENT_ USE Rejection: Set DUR_CONCURRENT_ OVR to 'OP_BUP'**
   - **For DUR_DD_DENY Rejection: Set OVR_RES to 'Y'**

   If the claim analysis continues to reject, follow the clinical coverage determination process.

   If no, do not approve.
   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and a buprenorphine-containing drug together.

   [Proceed to enter Denial Text below]

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPIOID-BUPRENORPHINE CONCURRENT USE** allows approval for use of an opioid with buprenorphine or a buprenorphine-containing agent together when ONE of the following rule(s) is met:
   A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   B. You are enrolled in a hospice (end of life care)
   C. You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
   D. You have sickle cell disease (a type of blood disorder)
   E. Your doctor confirms (attests) that you have discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and you need to resume chronic opioid treatment. Consultation with an addiction medicine specialist is recommended.
   F. Your doctor is aware that you are currently receiving buprenorphine or a buprenorphine-containing agent for treatment of opioid dependency and has confirmed to proceed with opioid treatment for an acute, clinically appropriate indication. Consultation with an addiction medicine specialist is recommended

   (Denial text continued on next page)

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OPIOID-BUPRENORPHINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

PARTIALLY APPROVED OPIOID TEXT:
Although we have entered a prior authorization for <DRUG+QL/UM (if any)> from <DATE RANGE>, your request has additional restrictions and criteria that you must meet as described above. You will be able to receive your medication once the additional criteria has been met and the restrictions have been removed.

PREVIOUSLY APPROVED OPIOID CLAIMS WITH NO PA, BUT NOW REJECTS DUE TO SAFETY EDIT TEXT:
Although you were previously approved for <DRUG> your new request now has additional safety restrictions that you must meet as described above. You will not be able to receive your medication until the newly added restrictions have been removed.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from CMS guidance. For further information, please refer to the Drug Monograph for Opioid-Buprenorphine Concurrent Use.

Prior authorization will be required for opioid prescriptions when in concurrent use with buprenorphine. This edit will be utilized to stop opioid claims, which overlap with buprenorphine use. The edit will stop the claim for pharmacy submission of PPS codes. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.

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OPIOID-BUPRENORPHINE CONCURRENT USE

RATIONALE (CONTINUED)

The guideline requires that the prescriber is aware that the patient is currently receiving buprenorphine or buprenorphine-containing agents for treatment of opioid dependency and has provided attestation to proceed with opioid treatment for an acute, clinically appropriate indication, or the prescriber has provided attestation that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and to proceed with opioid treatment. Consultation with an addiction medicine specialist is recommended.
In addition, the guideline allows an override for patients with one of the following conditions:
Receiving palliative care or end-of-life care
Enrolled in hospice
Resident of a long-term care facility or intermediate care for intellectually disabled
Diagnosis of sickle cell disease
Being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

REFERENCES

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CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-NAIVE CUMULATIVE DOSING (ONCD)

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?
   - The request is for an opioid product equal to or exceeding the soft-stop threshold or hard-stop threshold as noted in the POS reject messaging?
     NOTE: The following reject code(s) may also be present:
     - For Soft-Stop: **REJ-88-1080**
     - For Hard-Stop: **REJ-88-1081**

     If yes, continue to #2.
     If no, guideline does not apply.

2. Is the patient opioid-naive meaning they have not used an opioid drug(s) in the past 60 days (starting the day prior to the fill date of the incoming claim)?
   [NOTE: Please refer to the claims history in MedAcess, Medication Request Form (MRF) or chart notes (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, continue to #3.
   If no, **approve for one (1) month, for one (1) fill count by HICL or GPI-10 and set NAIVE_OP_HARD_LIMIT_OVR to 'Y' for Yes**.

3. Does the patient meet at least **ONE** of the following criteria?
   - The patient is enrolled in hospice
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set NAIVE_OP_HARD_LIMIT_OVR to 'Y' for Yes**.

   If no, continue to #4.

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OPIOID-NAIVE CUMULATIVE DOSING

GUIDELINES FOR USE (CONTINUED)

4. Have **BOTH** of the following criteria been met?
   - The provider has indicated that the patient's current level of opioid utilization is necessary and required for the level of pain management needed
   - The provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

   If yes, **approve for one (1) month, for one (1) fill count by HICL or GPI-10 and set NAIVE_OP_HARD_LIMIT_OVR to 'Y' for Yes**.

   If no, do not approve.
   OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
   [NOTE: Enter proactive PAs for other UM overrides not including Opioid-Naive Cumulative Dosing, if applicable.]

   While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because you are considered opioid naive (those who have not used opioid drugs within the past 60 days) and the opiate amount exceeds or is equal to **[enter soft stop threshold]**-mg morphine milligram equivalent (MME) or **[enter hard stop threshold]**-mg morphine milligram equivalent (MME). **[Proceed to enter Denial Text below]**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OPIOID-NAIVE CUMULATIVE DOSING** allows approval of a higher quantity of an opioid medication if at least ONE of the following conditions is met:
   - You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   - You are enrolled in hospice (end of life care)
   - You are a resident of (living in) a long-term care facility or intermediate care for intellectually disabled
   - You have sickle cell disease (a type of blood disorder)
   - You are not opioid naive (you have been consistently using opioid pain medications)
   - You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

   (Denial text continued on next page)

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OPIOID-NAIVE CUMULATIVE DOSING

GUIDELINES FOR USE (CONTINUED)

If none of these conditions apply, BOTH of the following criteria must be met:

- The provider has indicated that your current level of opioid utilization (use) is necessary and required for the level of pain management needed
- The provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

Please consult your physician and/or your pharmacist to discuss your options or if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

RATIONALE

To ensure appropriate use of opioids and address the prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.
The guideline is based on CDC dosage recommendations stated in the “Initial Opioid Prescribing at High Dosage” measures from the Pharmacy Quality Alliance (PQA) and Managed Medicaid program limits.

This requirement does not apply to patients in palliative care, hospice patients, patients living in a long-term care facility or intermediate care for intellectually disabled, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease.
In addition, approval is granted if BOTH of the following conditions are met:
The provider has indicated that the patient’s current level of opioid utilization is necessary and required for the level of pain management needed
The provider has committed to monitoring the state’s Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

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OPIOID-NAIVE CUMULATIVE DOSING

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Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-NAIVE DAY SUPPLY LIMITATION

Generic	Brand	HICL	GCN	Medi-Span	Exception/other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ-1044: INITIAL FILL DAYS SUPPLY EXCEEDS LIMITS (DS-NAIVE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is enrolled in hospice
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only
   - The patient is NOT opioid naive
     (**NOTE:** For new patients with no claims history, please refer to the MRF or MedAccess).

   If yes, **approve for one month, for one fill count by HICL or GPI-10 and set DS_NAIVE_OVR to 'Y' for Yes.**

   If no, continue to #3.

3. Has the prescriber provided attestation that the opioid medication with the requested day supply is the intended and medically necessary amount for the beneficiary?

   If yes, **approve for one month, for one fill count by HICL or GPI-10 and set DS_NAIVE_OVR to 'Y' for Yes.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-NAIVE DAY SUPPLY LIMITATION

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the day supply you are requesting for this opioid medication.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-NAIVE DAY SUPPLY LIMITATION** allows approval of the requested drug for a longer day supply when you meet at least **ONE** of the following conditions:

A. You are enrolled in hospice (end of life care)
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. You are NOT opioid naïve (you have been consistently using opioid pain medications)
F. Your doctor confirms (attests) that the prescribed dose of opioids with the requested day supply is intended and medically necessary
G. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your doctor if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this medication.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.

In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
“Beginning in 2019, we expect all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days’ supply…”. *CMS 2019 Call Letter, page 237*

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OPIOID-NAIVE DAY SUPPLY LIMITATION

RATIONALE (CONTINUED)

Prior authorization will be required for opioid prescriptions with a longer day supply for opioid naive patients. This requirement does not apply to patients receiving palliative care or end-of-life care, those enrolled in hospice, residents of a long-term care facility or intermediate care for intellectually disabled, or patients being treated for cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.

In addition, if the patient is determined to NOT be opioid naive during the coverage determination process, they are exempt from this safety edit. This exemption is based on the following guidance: "If during the coverage determination process, it becomes known that the patient is not opioid naive, he or she should be excluded from the opioid naive edit." *CMS Additional Guidance memo from October 23, 2018, page 8.*

Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. This guideline also allows an override when there is attestation from the prescriber that the prescribed dose of opioids with the requested day supply is intended and medically necessary.

REFERENCES

Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf [Accessed 4/2/18]

The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].

Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://mopa.memberclicks.net/assets/docs/Opioid_SafetyEdit_Memo_10232018%20%28002%29.pdf [Accessed 11/20/18].

CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary- level-opioid-point-sale-safety-edits-july-5-2024.pdf [Accessed 8/12/24].

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-SKELETAL MUSCLE RELAXANT CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ- 1209: OPIOID-SKELETAL MUSCLE RELAXANT CONFLICT FOUND (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient has sickle cell disease (ICD-10 Group D57)
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_SMR'.**
   If no, continue to #3.

3. Has the prescriber indicated that the concurrent use of an opioid and a skeletal muscle relaxant is intended and clinically appropriate for the patient?
   [NOTE: Refer to the Medical Request Form (MRF) or chart notes if provided (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'OP_SMR'.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-SKELETAL MUSCLE RELAXANT CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
[NOTE: Enter proactive PAs for other UM overrides not including the Opioid-Skeletal Muscle Relaxant Concurrent Use, if applicable.]
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid drug and a skeletal muscle relaxant together.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-SKELETAL MUSCLE RELAXANT CONCURRENT USE** allows an approval for use of an opioid with a skeletal muscle relaxant medication (type of pain medication) together when one of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice (end of life care)
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. You have sickle cell disease (a type of blood disorder)
E. Your doctor confirms that the use of an opioid and a skeletal muscle relaxant medication together is intended and clinically appropriate for you
F. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

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OPIOID-SKELETAL MUSCLE RELAXANT CONCURRENT USE

RATIONALE

To mitigate the risk of overdose from dangerous combinations of skeletal muscle relaxants and opioids while preserving patient access to drug regimens if deemed medically necessary.

REFERENCES

SUPPORT for Patients and Communities Act, H.R. 6, Section 1004, 115th Congress. (2018). Available at: https://www.congress.gov/bill/115th-congress/house-bill/6 . [Accessed 3/11/26].

CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 3/11/26].

Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary- level-opioid-point-sale-safety-edits-july-5-2024.pdf

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
N/A	N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
   - **REJ- 433-1204: SOMA-OPIOID-BENZODIAZEPINE CONFLICT FOUND (H: DUR_CONCURRENT_USE)**

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
   - The patient is in hospice care
   - The patient is receiving palliative care (ICD-10 Z51.5) or end-of-life care
   - The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
   - The patient is being treated for cancer-related pain which includes: those undergoing active cancer treatment, cancer survivors with chronic pain who have completed cancer treatment, those in clinical remission, or under cancer surveillance only

   If yes, **approve for 12 months by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'SOMA_OP_BZD'.**

   If no, continue to #3.

3. Has the prescriber indicated that the concurrent use of an opioid with Soma (carisoprodol) and a benzodiazepine medication is intended and clinically appropriate for the patient?

   [NOTE: Refer to the Medical Request Form (MRF) or chart notes if provided (e.g., patient is stable on the requested drug, patient needs to continue use, etc.). The member cannot provide this information.]

   If yes, **approve for one (1) month by HICL or GPI-10 and set DUR_CONCURRENT_OVR to 'SOMA_OP_BZD'.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:
[NOTE: Enter proactive PAs for other UM overrides not including Opioid-Soma-Benzodiazepine Concurrent Use, if applicable.]
While your request for **[enter approved UM]** for **[enter requested drug]** has been granted, the drug has not been approved because of the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together.

[Proceed to enter Denial Text below]

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE** allows an approval for use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together when one of the following criteria is met:

A. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
B. You are enrolled in a hospice
C. You are a resident of a long-term care facility or intermediate care for intellectually disabled
D. Your doctor confirms that the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together is intended and clinically appropriate for you
E. You are being treated for cancer-related pain which includes: you are undergoing active cancer treatment, you are a cancer survivor with chronic (long-term) pain and have completed cancer treatment, you are in clinical remission (reduction or disappearance of the signs and symptoms of a disease), or you are under cancer surveillance (monitoring) only

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

RATIONALE

To mitigate the risk of the overdose from dangerous combinations of CNS depressants while preserving patient access to drug regimens if deemed medically necessary.

The Opioid-Benzodiazepine-Soma Concurrent Use at POS edit will identify and deny concurrent use of opioids, benzodiazepines, and carisoprodol when there is an overlap in day supply (for at least one drug from each 'class'). This edit will reject the claim that creates the three-drug overlap.

The edit will have internal reject codes REJ- 433- 1204, and the following parameters:

1. Triple drug overlap = 1 day
2. Prescriber threshold = 1 prescriber
3. Exceptions =
   a) Cancer diagnosis (edit will lookback for presence of claims related to these diseases in the past 180 days to automatically exclude from the edit)
   b) Hospice or palliative care (edit will look for hospice attribute on claims to automatically exclude from the edit)
   c) Long Term Care residence (edit will look for patient residence code to automatically exclude from the edit)
   d) Cancer-related pain. Cancer-related pain includes those undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only

Please note that sickle cell disease will not be included in the exception criteria. Although opioids and benzodiazepines can be used in managing pain crises, treatment guidelines do not mention skeletal muscle relaxants such as carisoprodol as a typical treatment modality.

REFERENCES

Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary- level-opioid-point-sale-safety-edits-july-5-2024.pdf Accessed 8/14/24].

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ORFORGLIPRON

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ORFORGLIPRON CALCIUM	FOUNDAYO	51258		GPI-10 (6125206020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for weight loss OR weight management (ICD-10 Group E66) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - There is physician attestation of active enrollment in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
   - Foundayo will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (e.g., Zepbound [tirzepatide], Mounjaro [tirzepatide])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ORFORGLIPRON

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non- alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)

   If yes, **approve for 29 weeks by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ORFORGLIPRON (Foundayo)** requires the following rule(s) be met for approval:
   A. The request is for weight loss or weight management
   B. You are 18 years of age or older
   C. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
   D. You will NOT use Foundayo concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])

   (Initial denial text continued on next page)

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ORFORGLIPRON

INITIAL CRITERIA (CONTINUED)

E. You meet ONE of the following before starting weight loss therapy:
   1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
   2. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
   3. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
   4. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

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ORFORGLIPRON

RENEWAL CRITERIA

1. Is the request for weight loss OR weight management (ICD-10 Group E66) and the patient meets **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non- alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - Foundayo will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (e.g., Zepbound [tirzepatide], Mounjaro [tirzepatide])
   - The patient has achieved or maintained at least a 5% weight loss of baseline body weight

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ORFORGLIPRON

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ORFORGLIPRON (Foundayo)** requires the following rule(s) be met for approval:

A. The request is for weight loss or weight management
B. You meet ONE of the following before starting weight loss therapy:
    1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
    2. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
    3. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
    4. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
C. You will NOT use Foundayo concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
D. You have achieved or maintained at least a 5 percent weight loss of baseline (before treatment) body weight

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ORFORGLIPRON

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Foundayo.

REFERENCES

Foundayo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; April 2026.

Created: 06/26
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ORLISTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ORLISTAT	XENICAL, ORLISTAT		95213	GPI-14 (61253560000120)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for weight loss OR weight management (ICD-10 Group E66) **AND** the patient meets the following criterion?
   - There is physician attestation of active enrollment in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ORLISTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ORLISTAT (Xenical)** requires the following rule(s) be met for approval:

A. The request is for weight loss or weight management
B. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
C. You meet ONE of the following before starting weight loss therapy:
    1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
    2. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
    3. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
    4. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])

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ORLISTAT

RENEWAL CRITERIA

1. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient younger than 18 years of age **AND** meets the following criterion?
   - The patient has achieved or maintained at least a 5% decrease from baseline body mass index (BMI) after 3 months of treatment

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #3 per day.**
   If no, continue to #3.

3. Is the patient 18 years of age or older and meets **ONE** the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ORLISTAT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ORLISTAT (Xenical)** requires the following rule(s) be met for renewal:

A. The request is for weight loss or weight management

B. If you are younger than 18 years of age, renewal also requires:

1. You have achieved or maintained at least a 5% decrease from baseline body mass index (BMI: a tool for evaluating body fat) after 3 months of treatment

C. If you are 18 years of age or older, renewal also requires:

1. You meet ONE of the following before starting weight loss therapy:
   a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
   b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
   c. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
   d. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
2. You have achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenical.

REFERENCES

Xenical (orlistat) [Prescribing Information]. Montgomery, AL: H2-Pharma, LLC; July 2024.

Created: 05/24
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSILODROSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSILODROSTAT PHOSPHATE	ISTURISA	46396		GPI-10 (3002206060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's syndrome (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Surgery is not an option or has not been curative for the patient
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: oral ketoconazole, cabergoline

   If yes, **approve for 6 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **1mg: #8 per day.**
   - **5mg: #12 per day.**
   - **10mg: #6 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for approval:
   A. You have Cushing's syndrome (a type of hormone disorder)
   B. You are 18 years of age or older
   C. Surgery is not an option or has not cured your condition
   D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   E. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: oral ketoconazole, cabergoline

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSILODROSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's syndrome (ICD-10 Group E24) and meet **ALL** the following criteria?
   - The patient continues to have improvement of Cushing's disease/Cushing's syndrome (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Isturisa

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **1mg: #8 per day.**
   - **5mg: #12 per day.**
   - **10mg: #6 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for renewal:
   A. You have Cushing's syndrome (a type of hormone disorder)
   B. You continue to have improvement of Cushing's disease/Cushing's syndrome (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   C. You continue to tolerate treatment with Isturisa

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Isturisa.

REFERENCES

Isturisa [Prescribing Information]. Bridgewater, NJ: Recordati Rare Diseases, Inc.; November 2025.

Created: 08/20
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OSIMERTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSIMERTINIB MESYLATE	TAGRISSO	42803		GPI-10 (2136006820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
- The patient is 18 years of age or older

If yes, continue to #2.
If no, continue to #6.

2. Will Tagrisso be used as adjuvant therapy after tumor resection **AND** the patient meets the following criterion?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Is the cancer locally advanced and unresectable (stage III) and the patient meets **ALL** of the following criteria?
   - The patient's disease has NOT progressed during or following concurrent or sequential platinum-based (e.g., cisplatin, carboplatin) chemoradiation therapy
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Is the cancer metastatic and the patient meets **ONE** of the following criteria?
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test
   - The patient's tumor has an epidermal growth factor receptor (EGFR) T790M mutation, as detected by an FDA-approved test, AND the patient's disease has progressed while on or after EGFR tyrosine kinase-inhibitor therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #5.

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

5. Is the cancer locally advanced or metastatic and the patient meets **ALL** of the following criteria?
   - Tagrisso will be used in combination with pemetrexed and platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is the request for a currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document? (see FDA website for approved drugs indications: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OSIMERTINIB (Tagrisso)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Non-small cell lung cancer (NSCLC: a type of lung cancer)
      2. A currently approved US Food and Drug Administration (FDA) indication as listed in the recent manufacturer prescribing information document

   B. If you have non-small cell lung cancer, approval also requires:
      1. You are 18 years of age or older
      2. You meet ONE of the following:
         a. Tagrisso will be used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor), and your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)- approved test

(Denial text continued on next page)

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OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

b. Your cancer is locally advanced and unresectable (stage III) (cancer that has spread to nearby tissue or lymph nodes and cannot be surgically removed), and you meet ALL of the following:
   i. Your disease has NOT worsened during or following concurrent (at the same time) or sequential (one after the other) platinum-based (such as cisplatin, carboplatin) chemoradiation therapy (a type of treatment that combines chemotherapy and radiation)
   ii. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
c. Your cancer is metastatic (cancer that has spread to other parts of the body), and you meet ONE of the following:
   i. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   ii. Your tumor has an epidermal growth factor receptor (EGFR) T790M mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test, AND your disease has worsened while on or after EGFR tyrosine kinase-inhibitor therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])
d. Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body), and you meet ALL of the following:
   i. Tagrisso will be used in combination with pemetrexed and platinum-based chemotherapy (such as cisplatin, carboplatin)
   ii. Your tumor has epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tagrisso.

REFERENCES

Tagrisso [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.

Created: 11/15
Effective: 02/09/26 Client Approval: 02/26 P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OTESECONAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OTESECONAZOLE	VIVJOA	47976		GPI-10 (1140805000)	

GUIDELINES FOR USE

1. Is the request for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) (ICD-10 B37.32) and the patient meets **ALL** of the following criteria?
   - The patient is female
   - The patient is NOT of reproductive potential (defined as a biological female who is postmenopausal or has another reason for permanent infertility [e.g., tubal ligation, hysterectomy, salpingo-oophorectomy])
   - The patient is NOT currently on ibrexafungerp for RVVC

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received Vivjoa?

   If yes, continue to #4.
   If no, continue to #3.

3. Has the patient had 3 or more episodes of VVC in the past 12 months?

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #18 per 12 weeks.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient has successfully completed a course of Vivjoa for prevention of RVVC
   - The patient is either being treated or has just completed treatment for a new recurrence of VVC

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #18 per 12 weeks.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OTESECONAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OTESECONAZOLE (Vivjoa)** requires the following rule(s) be met for approval:

A. You have recurrent vulvovaginal candidiasis (RVVC: a repeating vaginal fungal infection)
B. You are female
C. You are not able to reproduce, which means you are a biological female and are postmenopausal (after menopause) or you have another reason for permanent infertility (such as tubal ligation [having tubes tied], hysterectomy [removal of the uterus], salpingo-oophorectomy [removal of an ovary and its fallopian tube])
D. You are NOT currently on ibrexafungerp for RVVC
E. If you have not previously received Vivjoa, approval also requires:
   1. You had 3 or more episodes of RVVC in the past 12 months
F. If you have previously received Vivjoa, approval also requires:
   1. You have successfully completed a course of Vivjoa for prevention of RVVC
   2. You are either being treated or have just completed treatment for a new recurrence of VVC

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vivjoa.

REFERENCES

Vivjoa [Prescribing Information]. Durham, NC: Mycovia Pharmaceuticals, Inc.; April 2024.

Created: 07/22
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OXYMETAZOLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OXYMETAZOLINE HCL/PF	UPNEEQ	46701		GPI-10 (8680223610)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of blepharoptosis (ICD-10 Groups H02.40, H02.41, H02.42, H02.43) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient has been evaluated for surgical intervention
   - The patient has experienced visual impairment due to blepharoptosis
   - The patient had a trial of TWO ophthalmic alpha-adrenergic agonists (e.g., apraclonidine, tetrahydrozoline, naphazoline)

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #1 droperette per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OXYMETAZOLINE (Upneeq)** requires the following rule(s) be met for approval:
   A. You have blepharoptosis (drooping of the upper eyelid)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or optometrist (a type of eye doctor)
   D. You have been evaluated for surgical intervention
   E. You have experienced visual impairment (limited or blocked vision) due to blepharoptosis (drooping of the upper eyelid)
   F. You have tried TWO ophthalmic alpha-adrenergic agonists (such as apraclonidine, tetrahydrozoline, naphazoline)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OXYMETAZOLINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of blepharoptosis (ICD-10 Groups H02.40, H02.41, H02.42, H02.43) **AND** meet the following criterion?
   - The patient continues to benefit from Upneeq

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 droperette per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OXYMETAZOLINE (Upneeq)** requires the following rule(s) be met for renewal:
   A. You have blepharoptosis (drooping of the upper eyelid)
   B. You continue to benefit from Upneeq

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Upneeq.

REFERENCES

Upneeq [Prescribing Information]. Bridgewater, NJ: RVL Pharmaceuticals, Inc.; May 2024.

Created: 11/21
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OZANIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OZANIMOD HYDROCHLORIDE	ZEPOSIA	46431		GPI-10 (6240705020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Zeposia will NOT be used concurrently with another systemic biologic (e.g., Tysabri [natalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of a relapsing form of MS

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have **ANY** of the following contraindications to Zeposia?
   - Within the last 6 months, experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure
   - A presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
   - Severe untreated sleep apnea
   - Concomitant use of a monoamine oxidase inhibitor (e.g., selegiline, phenelzine, linezolid)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

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OZANIMOD

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Zeposia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OZANIMOD

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. A relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have a relapsing form of multiple sclerosis, approval also requires:
   1. You are 18 years of age or older
   2. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Tysabri [natalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of a relapsing form of multiple sclerosis (a type of nerve disorder)
   3. You do NOT have any of the following contraindications to (harmful for you to use) Zeposia:
      a. Within the last 6 months, experienced a myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (TIA: short stroke-like attack), decompensated heart failure (a type of heart condition) requiring hospitalization, or Class III or IV heart failure (a type of heart condition)
      b. A presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block (types of irregular heartbeats), unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)
      c. Severe untreated sleep apnea (a type of sleep condition with difficulty breathing)
      d. Concomitant use (using at the same time) of a monoamine oxidase inhibitor (a type of medication such as selegiline, phenelzine, linezolid)

C. If you have moderate to severe ulcerative colitis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

(Initial denial text continued on next page)

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OZANIMOD

INITIAL CRITERIA (CONTINUED)

4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Skyrizi (risankizumab-rzaa)
   c. Tremfya (guselkumab)
   d. Omvoh (mirikizumab-mrkz)
   e. Adalimumab-ryvk/adalimumab-aaty
   f. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
   g. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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OZANIMOD

RENEWAL CRITERIA

NOTE: For the diagnosis of multiple sclerosis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Zeposia will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OZANIMOD

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for renewal:

A. You have moderate to severe ulcerative colitis (UC: a type of digestive disorder)
B. You will NOT use Zeposia concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
    1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
    2. Skyrizi (risankizumab-rzaa)
    3. Tremfya (guselkumab)
    4. Omvoh (mirikizumab-mrkz)
    5. Adalimumab-ryvk/adalimumab-aaty
    6. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
    7. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zeposia.

REFERENCES

Zeposia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; August 2024.

Created: 06/20
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 10/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PACLITAXEL PROTEIN-BOUND (NSA)

Generic	Brand	HICL	GCN	Medispan	Exception/Other
PACLITAXEL PROTEIN-BOUND	ABRAXANE	26856		GPI-10 (2150001220)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient previously tried a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) or paclitaxel?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more Information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) or Small Cell Lung Cancer (SCLC)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more Information, please ask your doctor or pharmacist.

   If no, continue to #4.

4. Does the patient have a diagnosis of metastatic adenocarcinoma of the pancreas?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PACLITAXEL PROTEIN-BOUND (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Is the requested medication being used in combination with gemcitabine?

If yes, **approve for 12 months by HICL or GPI-10.**
APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more Information, please ask your doctor or pharmacist.

If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PACLITAXEL (Abraxane)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   2. Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC: cancer that is in the advanced stage or that has spread to other parts of the body)
   3. Small Cell Lung Cancer (SCLC)
   4. Metastatic adenocarcinoma of the pancreas (pancreas cancer that has spread to other parts of the body)

B. If you have metastatic breast cancer, approval also requires:
   1. You have tried a chemotherapy regimen (cancer-treating medications) containing an anthracycline (cancer drug such as doxorubicin or epirubicin) or paclitaxel

C. If you have metastatic adenocarcinoma of the pancreas, approval also requires:
   1. The requested medication will be used in combination with gemcitabine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Abraxane.

REFERENCES

Abraxane [Prescribing Information]. Summit, NJ: Celegene Corporation; December 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 08/13
Client Approval: 04/20
P&T Approval: 11/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PACRITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PACRITINIB CITRATE	VONJO	47850		GPI-10 (2153755010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) (ICD-10 D47.1, D75.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a platelet count below 50,000/uL

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do no approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PACRITINIB (Vonjo)** requires the following rule(s) be met for approval:
   A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [a type of blood cell disorder] or post-essential thrombocythemia [a type of blood cell disorder]) myelofibrosis (MF: a type of blood cancer)
   B. You are 18 years of age or older
   C. You have a platelet count below 50,000/uL

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PACRITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) (ICD-10 D47.1, D75.81)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has a spleen volume reduction of at least 35% from baseline
   - The patient has at least a 50% reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has at least a 50% reduction in palpable spleen length

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PACRITINIB (Vonjo)** requires the following rule(s) be met for renewal:
   A. You have intermediate- or high-risk primary or secondary (post-polycythemia vera [a type of blood cell disorder] or post-essential thrombocythemia [a type of blood cell disorder]) myelofibrosis (MF: a type of blood cancer)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have a spleen volume reduction of at least 35% from baseline (before treatment)
      2. You have at least a 50% reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      3. You have at least a 50% reduction in palpable (can be felt by external examination) spleen length

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PACRITINIB

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Vonjo.

REFERENCES
Vonjo [Prescribing Information]. Waltham, MA: Sobi, Inc.; October 2025.

Created: 03/22
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALBOCICLIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALBOCICLIB	IBRANCE	41725		GPI-10 (2153106000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's cancer hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative?

   If yes, continue to #3.
   If no, continue to #6.

3. Will Ibrance be used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) as initial endocrine-based therapy and the patient meets **ALL** of the following criteria?
   - The patient's cancer is advanced or metastatic
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Kisqali (ribociclib), Verzenio (abemaciclib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, continue to #4.

4. Will Ibrance be used in combination with fulvestrant (Faslodex) and the patient meets **ALL** of the following criteria?
   - The patient's cancer is advanced or metastatic
   - The patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Kisqali (ribociclib), Verzenio (abemaciclib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, continue to #5.

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PALBOCICLIB

GUIDELINES FOR USE (CONTINUED)

5. Will Ibrance be used in combination with Itovebi (inavolisib) and fulvestrant (Faslodex) and the patient meets **ALL** of the following criteria?
   - The patient's cancer is locally advanced or metastatic
   - The patient's tumor has a PIK3CA mutation, as detected by an FDA-approved test
   - The patient has experienced disease recurrence on or after completing an adjuvant endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Is the patient’s cancer hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-positive and the patient meets **ALL** of the following criteria?
   - The patient’s cancer is locally advanced or metastatic
   - Ibrance will be used in combination with trastuzumab (Herceptin or an FDA-approved biosimilar) and endocrine therapy (e.g., letrozole, anastrozole, exemestane, fulvestrant) following induction treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PALBOCICLIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT:

Our guideline named **PALBOCICLIB (Ibrance)** requires the following rule(s) be met for approval:

A. You have breast cancer

B. If your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative, approval also requires ONE of the following:

1. Ibrance will be used in combination with an aromatase inhibitor (such as anastrozole, letrozole, exemestane) as initial endocrine (hormone)-based therapy; your cancer is advanced or metastatic (cancer that has progressed or has spread to other parts of the body); and you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kisqali (ribociclib), Verzenio (abemaciclib)
2. Ibrance will be used in combination with fulvestrant (Faslodex); your cancer is advanced or metastatic (cancer that has progressed or has spread to other parts of the body); your disease has worsened after endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen); and you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kisqali (ribociclib), Verzenio (abemaciclib)
3. Ibrance will be used in combination with Itovebi (inavolisib) and fulvestrant (Faslodex); your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body); your tumor has a PIK3CA mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test; and you have experienced disease recurrence (disease has returned) on or after completing adjuvant (add-on) endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)

C. If your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, approval also requires:

1. Your cancer is locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
2. Ibrance will be used in combination with trastuzumab (Herceptin or a Food and Drug Administration [FDA]-approved biosimilar) and endocrine (hormone) therapy (such as letrozole, anastrozole, exemestane, fulvestrant) following induction (initial) treatment

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibrance.

REFERENCES

Ibrance [Prescribing Information]. New York, NY: Pfizer Laboratories; June 2026.

Created: 05/15
Effective: 07/06/26 Client Approval: 07/26 DMC Approval: 07/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALIVIZUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALIVIZUMAB	SYNAGIS	18564		GPI-10 (1950206000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received Beyfortus (nirsevimab-alip) within this RSV season?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the patient under 12 months of age?

   If yes, continue to #3.
   If no, continue to #10.

3. Does the patient have chronic lung disease of prematurity (previously called bronchopulmonary dysplasia [BPD]) as defined below?
   - Gestational age less than 32 weeks, and
   - Patient required greater than 21% supplemental oxygen for at least the first 28 days after birth (**Note:** This does not include respiratory distress in the newborn, wheezing, reactive airway disease (RAD), asthma, or cystic fibrosis. Current data does not support the routine use of palivizumab prophylaxis in patients with cystic fibrosis.)

   If yes, continue to #12.
   If no, continue to #4.

4. Does the patient meet **ONE** of the following?
   - The patient is profoundly immunocompromised during the RSV season
   - The patient has undergone solid-organ transplantation during the RSV season

   If yes, continue to #12.
   If no, continue to #5.

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PALIVIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have **ONE** of the following congenital heart disease conditions?
   - Acyanotic heart disease requiring medication to control chronic heart failure (i.e., furosemide, epinephrine, dopamine, lidocaine, milrinone, atenolol, propranolol, amlodipine, clonidine) AND will require cardiac surgical procedures
   - Moderate or severe pulmonary hypertension
   - Cyanotic heart defect AND the requested medication is prescribed by or in consultation with a pediatric cardiologist
     (**Note:** This does not include patients with hemodynamically insignificant heart disease, infants with lesions adequately corrected by surgery, infants with mild cardiomyopathy who are not receiving medical therapy for the condition.)

   If yes, continue to #12.
   If no, continue to #6.

6. Was the patient born prematurely?

   If yes, continue to #8.
   If no, continue to #7.

7. Does the patient have congenital abnormalities of the airways (anatomic pulmonary abnormalities) or neuromuscular disease that compromises the handling of respiratory secretions?

   If yes, continue to #12.
   If no, continue to #8.

8. Was the patient born at less than 29 weeks gestational age?

   If yes, continue to #12.
   If no, continue to #9.

9. Does the patient meet **ONE** of the following?
   - The patient is an American Navajo infant
   - The patient is an American White Mountain Apache infant
   - The patient is an Alaska native infant

   If yes, continue to #12.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PALIVIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

10. Is the patient younger than 24 months of age?

    If yes, continue to #11.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

11. Does the patient meet **ONE** of the following criteria?
    - The patient is profoundly immunocompromised during the RSV season
    - The patient has chronic lung disease of prematurity **AND** requires medical support (oxygen, bronchodilator [e.g., albuterol], diuretic [e.g., furosemide], or chronic steroid therapy [e.g., budesonide]) within 6 months prior to the start of the second RSV season
    - The patient has undergone solid-organ transplantation during RSV season

    If yes, continue to #12.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

12. Approve by GPID or GPI-14, for all strengths, for 5 fills, as follows:

- **Start Date (Choose ONE):**
  - For requests with a start date of October 1st or further into the RSV season, enter the start date as requested.
    OR
  - For requests with a start date BEFORE October 1st, refer to the CDC website to verify whether RSV cases have started to increase in that region by confirming when the 'detections' (i.e., positive cases) begin to increase. If the detections have increased from baseline as of the date of the request, enter the start date as requested.
- **Approval Duration (Choose ONE):**
  - For requests that extend past April 30th, refer to the CDC website to verify when the RSV season for the specified region ends by confirming when the 'detections' (i.e., positive cases) returned to baseline in the previous years. If the detections returned to baseline after April 30th, enter a duration up to 5 months, but do not extend beyond the time when detections returned to baseline. (For example, if the request is received in February, and the CDC website shows that detection returned to baseline in that region in May of the previous year; then approve for 4 months).

    OR

  - Enter an approval duration up to April 30th.

NOTE: CDC website - https://www.cdc.gov/surveillance/nrevss/rsv/region.html

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PALIVIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for approval:

A. You have not received Beyfortus (nirsevimab-alip) within this RSV (type of lung and respiratory tract infection) season
B. You are less than 12 months old or less than 24 months at the start of respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season (mid-September to mid-May)
C. **If you are less than 12 months old, you must meet ONE of the following**:
   1. You have chronic lung disease of prematurity (a condition where you were born at less than 32 weeks and required more than 21% of additional oxygen for at least the first 28 days after birth)
   2. You are profoundly immunocompromised during RSV season (your body cannot fight off infections)
   3. You have received a solid-organ transplant during RSV season
   4. You have congenital (starting from birth) heart disease conditions at birth such as: acyanotic heart disease (blood from the left side to the right side of the heart due to a hole in the heart walls) where you need medication to control chronic heart failure and will require heart surgical procedures; moderate to severe pulmonary hypertension (high blood pressure in the lungs); or cyanotic heart defect (low blood oxygen level) and the requested medication is prescribed by or given in consultation with a pediatric cardiologist (a heart doctor for children)
   5. You have congenital (starting from birth) abnormalities of the lung airways or a neuromuscular (nerve-muscle) disorder that affects respiratory (lung/breathing) secretions
   6. You were born premature at less than 29 weeks (gestational age)
   7. You are an American Navajo, American White Mountain Apache, or Alaska Native infant born prematurely
D. If you are less than 24 months old, you must meet ONE of the following:
   1. You are profoundly immunocompromised during RSV season (a condition where your body cannot fight off infections)
   2. You have chronic lung disease of prematurity and need medical support within 6 months before the start of the second respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season. Medical support includes oxygen, bronchodilator (drug that helps you breathe such as albuterol), diuretic (drug that makes you urinate such as furosemide), or chronic steroid therapy (such as budesonide)
   3. You have received a solid-organ transplant during RSV season

(Initial denial text continued on next page)

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PALIVIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PALIVIZUMAB (NSA)

RENEWAL CRITERIA

1. Has the patient received Beyfortus (nirsevimab-alip) within this RSV season?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Is the patient younger than 24 months of age?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Did the patient undergo cardiopulmonary bypass surgery during their RSV prophylaxis season?

   If yes, **approve for 1 month by GPID or GPI-14 with a fill count of 2 (do not enter quantity limit on number of vials).**
   If no, continue to #4.

4. Is this a request for a second year of coverage (e.g., a previous approval in the previous RSV season)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have chronic lung disease of prematurity (previously called bronchopulmonary dysplasia [BPD]) and requires medical support (oxygen, bronchodilator [e.g., albuterol], diuretic [e.g., furosemide], or chronic steroid therapy [e.g., budesonide]) within 6 months prior to start of the second RSV season?
   (**Note:** This does not include respiratory distress in the newborn period, wheezing, reactive airway disease (RAD), asthma, or cystic fibrosis. Current data does not support the routine use of palivizumab prophylaxis in patients with cystic fibrosis.)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

6. Approve by GPID or GPI-14, for all strengths, for 5 fills, as follows:

- **Start Date (Choose ONE):**
  - For requests with a start date of October 1st or further into the RSV season, enter the start date as requested.

    OR

  - For requests with a start date BEFORE October 1st, refer to the CDC website to verify whether RSV cases have started to increase in that region by confirming when the 'detections' (i.e., positive cases) begin to increase. If the detections have increased from baseline as of the date of the request, enter the start date as requested.

- **Approval Duration (Choose ONE):**
  - For requests that extend past April 30th, refer to the CDC website to verify when the RSV season for the specified region ends by confirming when the 'detections' (i.e., positive cases) returned to baseline in the previous years. If the detections returned to baseline after April 30th, enter a duration up to 5 months, but do not extend beyond the time when detections returned to baseline. (For example, if the request is received in February, and the CDC website shows that detection returned to baseline in that region in May of the previous year; then approve for 4 months).

    OR

  - Enter an approval duration up to April 30th.

NOTE: CDC website - https://www.cdc.gov/surveillance/nrevss/rsv/region.html

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PALIVIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for renewal:

A. You have not received Beyfortus (nirsevimab-alip) within this RSV (type of lung and respiratory tract infection) season
B. You are under 24 months old
C. You meet **ONE** of the following:
   1. You received cardiopulmonary bypass surgery (type of heart and lung surgery) during respiratory syncytial virus prevention season
   2. This request is for a second year of coverage and you have chronic lung disease of prematurity and need medical support during the 6 months before the start of the second RSV season. Medical support includes oxygen, bronchodilator (drug that helps you breathe such as albuterol), diuretic (drug that makes you urinate such as furosemide), or chronic steroid therapy (such as budesonide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Synagis.

REFERENCES

Synagis [Prescribing Information]. Waltham, MA: Sobi Inc.; November 2021.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 09/11/23
Created: 08/09
Client Approval: 08/23
P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALOPEGTERIPARATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALOPEGTERIPARATIDE	YORVIPATH	49810		GPI-10 (3090516000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hypoparathyroidism (ICD-10 Group E20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis
   - The patient had a trial of activated vitamin D (e.g., calcitriol) and calcium

   If yes, **approve all strengths for 6 months by GPID or GPI-14 with a quantity limit as follows:**
   - **168 mcg/0.56 mL: #1.12 mL per 28 days.**
   - **294 mcg/0.98 mL: #1.96 mL per 28 days.**
   - **420 mcg/1.4 mL: #2.8 mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALOPEGTERIPARATIDE (Yorvipath)** requires the following rule(s) be met for approval:
   A. You have hypoparathyroidism (low levels of parathyroid hormone)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. Your hypoparathyroidism is NOT due to impaired responsiveness to parathyroid hormone or a history of disease that affects calcium metabolism or calcium-phosphate homeostasis (balance)
   E. You have tried activated vitamin D (such as calcitriol) and calcium

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALOPEGTERIPARATIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hypoparathyroidism (ICD-10 Group E20) **AND** meet the following criterion?
   - The patient is independent of or managed on a lowered dose of vitamin D and calcium supplementation

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **168 mcg/0.56 mL: #1.12 mL per 28 days.**
   - **294 mcg/0.98 mL: #1.96 mL per 28 days.**
   - **420 mcg/1.4 mL: #2.8 mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALOPEGTERIPARATIDE (Yorvipath)** requires the following rule(s) be met for renewal:
   A. You have hypoparathyroidism (low levels of parathyroid hormone)
   B. You are independent of or managed on a lowered dose of vitamin D and calcium supplements

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yorvipath.

REFERENCES

Yorvipath [Prescribing Information]. Princeton, NJ: Ascendis Pharma; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/23/24
Created: 09/24
Client Approval: 09/24
P&T Approval: 04/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALOVAROTENE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALOVAROTENE	SOHONOS	49043		GPI-10 (7588606000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of fibrodysplasia ossificans progressiva (FOP) (ICD-10 Group M61.1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a geneticist, orthopedist, rheumatologist, or a FOP specialty center

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient a male **AND** meets the following criterion?
   - The patient is 10 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient a female **AND** meets the following criterion?
   - The patient is 8 years of age or older

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient of reproductive potential?

   If yes, continue to #5.
   If no, **approve for 12 months by HICL or GPI-10.**

5. Has the patient obtained a negative pregnancy test within 7 days prior to initiating Sohonos?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PALOVAROTENE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PALOVAROTENE (Sohonos)** requires the following rule(s) be met for approval:

A. You have fibrodysplasia ossificans progressiva (FOP: a type of rare genetic tissue disorder)
B. Therapy is prescribed by or in consultation with a geneticist (doctor who treats gene disorders), orthopedist (a type of doctor who specializes in bones, joints, muscles, ligaments, tendons and nerves), rheumatologist (a type of immune system doctor), or a fibrodysplasia ossificans progressiva (FOP: a type of rare genetic tissue disorder) specialty center
C. You meet ONE of the following:
    1. You are a female AND 8 years of age or older
    2. You are a male AND 10 years of age or older
D. If you are a female of reproductive potential, you must have obtained a negative pregnancy test within 7 days prior to starting Sohonos

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PALOVAROTENE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of fibrodysplasia ossificans progressiva (FOP) (ICD-10 Group M61.1) **AND** meet the following criterion?
   - The patient has experienced a positive clinical response to therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALOVAROTENE (Sohonos)** requires the following rule(s) be met for renewal:
   A. You have fibrodysplasia ossificans progressiva (FOP: a type of rare genetic tissue disorder)
   B. You have experienced a positive clinical response to therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sohonos.

REFERENCES

Sohonos [Prescribing Information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; March 2025.

Created: 10/23
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PALTUSOTINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PALTUSOTINE HCL	PALSONIFY	50910		GPI-10 (3017007310)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient had an inadequate response to surgery OR surgery is not an option for this patient
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patient's age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Mycapssa, Sandostatin LAR Depot (octreotide acetate ER)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **20mg: #2 per day.**
   - **30mg: #4 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALTUSOTINE (Palsonify)** requires the following rule(s) be met for approval:
   A. You have acromegaly (a type of hormone disorder)
   B. You had an inadequate response (did not work) to surgery OR surgery is not an option for you
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   D. Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
   E. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mycapssa, Sandostatin LAR Depot (octreotide acetate ER)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PALTUSOTINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or has sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **20mg: #2 per day.**
   - **30mg: #4 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PALTUSOTINE (Palsonify)** requires the following rule(s) be met for renewal:
   A. You have acromegaly (a type of hormone disorder)
   B. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   C. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palsonify.

REFERENCES

Palsonify [Prescribing Information]. San Diego, CA: Crinetics Pharmaceuticals, Inc.; September 2025.

Created: 10/25
Effective: 10/20/25 Client Approval: 10/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PANITUMUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PANITUMUMAB	VECTIBIX	34054		GPI-10 (2136007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patien'ts cancer wild-type RAS (defined as wild-type in both KRAS and NRAS), as determined by an FDA-approved test?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - Vectibix will be used in combination with FOLFOX (leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)
   - Vectibix will be used as monotherapy AND the patient has disease progression after treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient's cancer have a KRAS G12C-mutation, as determined by an FDA-approved test, and meet **ALL** of the following criteria?
   - Vectibix will be used in combination with Lumakras (sotorasib)
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PANITUMUMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PANITUMUMAB (Vectibix)** requires the following rule(s) be met for approval:

A. You have metastatic colorectal cancer (mCRC: a type of digestive cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. Your cancer is wild-type RAS (defined as wild-type in both KRAS and NRAS [types of genes without a specific mutation]), OR you have a KRAS G12C-mutation [type of abnormal change in a gene], as determined by a Food and Drug Administration (FDA)-approved test
D. If your cancer is wild-type RAS, approval also requires ONE of the following:
   1. Vectibix will be used in combination with FOLFOX (treatment regimen containing leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)
   2. Vectibix will be used as monotherapy (one drug treatment) AND you have disease progression (worsening) after treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy (drugs used to treat cancer)
E. If your cancer has a KRAS G12C-mutation, approval also requires:
   1. Vectibix will be used in combination with Lumakras (sotorasib)
   2. You have received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vectibix.

REFERENCES

Vectibix [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; January 2025.

Created: 02/13
Effective: 02/24/25 Client Approval: 02/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PARATHYROID HORMONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PARATHYROID HORMONE	NATPARA	34000		GPI-10 (3004405510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypocalcemia (ICD-10 E83.51) secondary to hypoparathyroidism (ICD-10 Group E20) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of activated vitamin D (calcitriol) and calcium
   - The patient's hypoparathyroidism is NOT due to a calcium sensing receptor (CSR) mutation
   - The patient's hypoparathyroidism is NOT considered acute post-surgical hypoparathyroidism (surgery in the past 30 days)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **PARATHYROID HORMONE (Natpara)** requires the following rule(s) be met for approval:
   A. You have hypocalcemia secondary to hypoparathyroidism (low blood calcium due to low levels of a type of hormone)
   B. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   C. You have tried activated vitamin D (calcitriol) and calcium
   D. Your hypoparathyroidism (low levels of a type of hormone) is NOT due to a calcium sensing receptor (CSR) mutation (an abnormal change in a type of gene)
   E. Your hypoparathyroidism is NOT considered acute post-surgical hypoparathyroidism (low levels of a type of hormone due to surgery in the past 30 days)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Natpara.

REFERENCES

Natpara [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals, Inc.; May 2023.

Created: 04/15
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 05/15

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PASIREOTIDE DIASPARTATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PASIREOTIDE DIASPARTATE	SIGNIFOR	39866		GPI-10 (3017007520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cushing's disease (CD) (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has undergone non-curative pituitary surgery or pituitary surgery is not an option
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to oral ketoconazole

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2mL per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE DIASPARTATE (Signifor)** requires the following rule(s) be met for approval:
   A. You have Cushing's disease (CD: a type of hormone disorder)
   B. You are 18 years of age or older
   C. You have undergone non-curative pituitary (a major hormone producing gland) surgery OR pituitary surgery is not an option
   D. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   E. You have tried or have a contraindication to (harmful for you to use) ketoconazole

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PASIREOTIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Cushing's disease (CD) (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Signifor

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE DIASPARTATE (Signifor)** requires the following rule(s) be met for renewal:
   A. You have Cushing's disease (CD: a type of hormone disorder)
   B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
   C. You continue to tolerate treatment with Signifor

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Signifor.

REFERENCES

Signifor [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.

Created: 05/13
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PASIREOTIDE PAMOATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PASIREOTIDE PAMOATE	SIGNIFOR LAR	41635		GPI-10 (3017007540)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient had an inadequate response to surgery, or surgery is not an option for this patient
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patient's age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load
   - The patient had a trial of or contraindication to the preferred agent: Sandostatin LAR Depot (octreotide acetate ER)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Cushing's disease (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient has undergone non-curative pituitary surgery, or pituitary surgery is not an option for this patient
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient had a trial of or contraindication to oral ketoconazole

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PASIREOTIDE PAMOATE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PASIREOTIDE PAMOATE (Signifor LAR)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Acromegaly (a type of hormone disorder)
   2. Cushing's disease (a type of hormone disorder)

B. If you have acromegaly, approval also requires:
   1. You had an inadequate response (did not work) to surgery, or surgery is not an option for you
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Sandostatin LAR Depot (octreotide acetate ER)

C. If you have Cushing's disease, approval also requires:
   1. You have undergone non-curative pituitary (a major hormone producing gland) surgery, or pituitary surgery is not an option for you
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. You have tried or have a contraindication to (harmful for you to use) oral ketoconazole

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PASIREOTIDE PAMOATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or has sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 28 days.** If no, continue to #2.

2. Does the patient have a diagnosis of Cushing's disease (ICD-10 Group E24) and meet **ALL** of the following criteria?
   - The patient continues to have improvement of Cushing's disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol or improvements in signs and symptoms of disease)
   - The patient maintains tolerability to Signifor LAR

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PASIREOTIDE PAMOATE (Signifor LAR)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Acromegaly (a type of hormone disorder)
      2. Cushing's disease (a type of hormone disorder)

   B. If you have acromegaly, renewal also requires:
      1. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
      2. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

   C. If you have Cushing's disease, renewal also requires:
      1. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
      2. You continue to tolerate Signifor LAR

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PASIREOTIDE PAMOATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Signifor LAR.

REFERENCES

Signifor LAR [Prescribing Information]. Bridgewater, NJ: Recordati Rare Diseases Inc.; July 2024.

Created: 05/22
Effective:01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PATIROMER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PATIROMER CALCIUM SORBITEX	VELTASSA	42767		GPI-10 (9945006020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hyperkalemia (ICD-10 E87.5) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist or cardiologist
   - Veltassa is NOT being used as an emergency treatment for life-threatening hyperkalemia
   - The patient is NOT currently receiving dialysis
   - Veltassa will NOT be used concurrently with another potassium binder (e.g., Lokelma [sodium zirconium cyclosilicate], sodium polystyrene sulfonate)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried **ONE** of the following approaches to reduce the modifiable risks for hyperkalemia?
   - The patient is not taking both an angiotensin converting enzyme inhibitor (ACE-I; e.g., lisinopril, benazepril) and an angiotensin receptor blocker (ARB; e.g., valsartan, losartan) at the same time
   - The patient has reduced the dose of a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g., lisinopril, valsartan, spironolactone)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have an estimated glomerular filtration rate (eGFR) of less than 30mL/min/1.73m(2) **AND** meet the following criterion?
   - The patient has tried a loop diuretic (e.g., bumetanide, furosemide, torsemide)

   If yes, continue to #5.
   If no, continue to #4.

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PATIROMER

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have an estimated glomerular filtration rate (eGFR) of at least 30mL/min/1.73m(2) and meet **ONE** of the following criteria?
   - The patient has tried a loop diuretic (e.g., bumetanide, furosemide, torsemide)
   - The patient has tried a thiazide diuretic (e.g., chlorthalidone, hydrochlorothiazide, metolazone)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - The patient is 12 to 17 years of age
   - The patient is 18 years of age or older AND had a trial of Lokelma (sodium zirconium cyclosilicate)

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **1 gm: #12 per day.**
   - **8.4 gm: #1 per day.**
   - **16.8 gm: #1 per day.**
   - **25.2 gm: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PATIROMER (Veltassa)** requires the following rule(s) be met for approval:
   A. You have hyperkalemia (high level of potassium in the blood)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor) or cardiologist (a type of heart doctor)
   D. Veltassa is NOT being used as an emergency treatment for life-threatening hyperkalemia (high level of potassium in the blood)
   E. You are NOT currently receiving dialysis (process of removing excess water, toxins from the blood)
   F. You will NOT use Veltassa concurrently (at the same time) with another potassium binder (such as Lokelma [sodium zirconium cyclosilicate], sodium polystyrene sulfonate)

   (Denial text continued on next page)

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PATIROMER

GUIDELINES FOR USE (CONTINUED)

G. You have tried ONE of the following to lower the risks for hyperkalemia (high level of potassium in the blood):
   1. You are not taking both an angiotensin converting enzyme inhibitor (ACE-I, such as lisinopril, benazepril) and an angiotensin receptor blocker (ARB, such as valsartan, losartan) at the same time
   2. You have lowered the dose of a renin-angiotensin-aldosterone system (RAAS) inhibitor (such as lisinopril, valsartan, spironolactone)

H. You meet ONE of the following:
   1. Your estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) is less than 30mL/min/1.73m(2), AND you have tried a loop diuretic (such as bumetanide, furosemide, torsemide)
   2. Your estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) is at least 30 mL/min/1.73m(2), AND you have tried a loop diuretic (such as bumetanide, furosemide, torsemide) OR a thiazide diuretic (such as chlorthalidone, hydrochlorothiazide, metolazone)

I. If you are 18 years of age or older, you have tried Lokelma (sodium zirconium cyclosilicate)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Veltassa.

REFERENCES

Veltassa [Prescribing Information]. Redwood City, CA: Vifor Pharma, Inc.; October 2023.

Created: 2/16
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PATISIRAN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PATISIRAN SODIUM, LIPID COMPLEX	ONPATTRO	45155		GPI-10 (6270606010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   - The patient is ambulatory (i.e., Familial Amyloid Polyneuropathy [FAP] stage 1 - 2 or Polyneuropathy Disability [PND] Stage I - IIIb polyneuropathy)
   - Onpattro will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Tegsedi [inotersen], Amvuttra [vutrisiran])
   - The patient had a trial of or contraindication to the preferred agent: Amvuttra (vutrisiran)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the hATTR diagnosis confirmed by **ONE** of the following?
   - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
   - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #15mL per 21 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PATISIRAN (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PATISIRAN (Onpattro)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
D. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 or Polyneuropathy Disability [PND: a tool used to evaluate disease severity] Stage I to IIIb polyneuropathy)
E. You will NOT use Onpattro concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Tegsedi [inotersen], Amvuttra [vutrisiran])
F. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Amvuttra (vutrisiran)
G. Your diagnosis is confirmed by ONE of the following:
    1. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm the presence of TTR (transthyretin) protein
    2. DNA genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PATISIRAN (NSA)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient has NOT progressed to Familial Amyloid Polyneuropathy (FAP) stage 3 or Polyneuropathy Disability (PND) Stage IV polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   - Onpattro will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Tegsedi [inotersen], Amvuttra [vutrisiran])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 21 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PATISIRAN (Onpattro)** requires the following rule(s) be met for renewal:
   A. You have hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
   B. You have NOT progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 OR Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage IV polyneuropathy as shown by functional decline (such as being wheelchair-bound or bedridden)
   C. You will NOT use Onpattro concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Tegsedi [inotersen], Amvuttra [vutrisiran])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PATISIRAN (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Onpattro.

REFERENCES

Onpattro [Prescribing Information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; January 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 08/18
Client Approval: 05/24
P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PAZOPANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PAZOPANIB HCL	VOTRIENT, PAZOPANIB HCL	36709		GPI-10 (2153304210)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Adipocytic soft tissue sarcoma (STS)
   - Gastrointestinal stromal tumors (GIST) (ICD-10 Group C49.A)

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced soft tissue sarcoma (STS) (ICD-10 Group C49, except Group C49.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received prior chemotherapy (e.g., doxorubicin, epirubicin)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **200mg: #4 per day.**
   - **400mg: #2 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **200mg: #4 per day.**
   - **400mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PAZOPANIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PAZOPANIB (Votrient)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced soft tissue sarcoma (STS: a type of cancer that starts in soft tissues [muscle, tendons, fat, lymph vessels, blood vessels, nerves])
   2. Advanced renal cell carcinoma (RCC: a type of kidney cancer)

B. If you have advanced soft tissue sarcoma, approval also requires:
   1. You are 18 years of age or older
   2. You have received prior chemotherapy (a type of cancer therapy such as doxorubicin, epirubicin)
   3. You do NOT have adipocytic soft tissue sarcoma (STS: a type of fat cell cancer) or gastrointestinal stromal tumors (GIST: a type of digestive tumor)

C. If you have advanced renal cell carcinoma, approval also requires:
   1. You are 18 years of age or older

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Votrient.

REFERENCES

Votrient [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.

Created: 05/11
Effective: 12/01/25 Client Approval: 11/25 P&T Approval: 08/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEANUT ALLERGEN POWDER-DNFP

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEANUT ALLERGEN POWDER-DNFP	PALFORZIA	46332		GPI-10 (2010004020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a peanut allergy (ICD-10 Z91.010) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - Therapy is prescribed by or in consultation with an allergist or immunologist
   - The patient has a clinical history of an allergic reaction to peanuts
   - Palforzia will be used in conjunction with a peanut-avoidance diet
   - Palforzia will NOT be used concurrently with a peanut-specific immunotherapy (e.g., Viaskin Peanut)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient completed a purposeful food challenge?

   If yes, continue to #3.
   If no, continue to #4.

3. Is the patient's diagnosis confirmed by **ONE** of the following criteria?
   - The patient tested positive on a skin prick test with a wheal diameter of at least 3 mm within the past 24 months
   - The patient has had a peanut-specific immunoglobulin E (IgE) level of at least 0.35 kUA/L within the past 24 months

   If yes, **approve all of the following for 12 months by GPID or GPI-14 as follows:**
   - **300 mg powder packet/sachet: #1 per day.**
   - **All other strengths: No quantity limit.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PEANUT ALLERGEN POWDER-DNFP

INITIAL CRITERIA (CONTINUED)

4. Is the patient's diagnosis confirmed by **ONE** of the following criteria?
   - The patient tested positive on a skin prick test with a wheal diameter of at least 8 mm within the past 24 months
   - The patient has had a peanut-specific immunoglobulin E (IgE) level of at least 14 kUA/L within the past 24 months

   If yes, **approve all of the following for 12 months by GPID or GPI-14 as follows:**
   - **300 mg powder packet/sachet: #1 per day.**
   - **All other strengths: No quantity limit.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for approval:
   A. You have an allergy to peanuts
   B. You are 1 to 17 years of age
   C. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
   D. You have a clinical history of an allergic reaction to peanuts
   E. Palforzia will be used together with a peanut-avoidance diet
   F. Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
   G. Your diagnosis is confirmed by ONE of the following:
      1. If you have completed a purposeful food challenge (a type of test): you had a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm within the past 24 months, OR you have had a peanut-specific immunoglobulin E (IgE) (a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
      2. If you have NOT completed a purposeful food challenge (a type of test): you had a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm within the past 24 months, OR you have had a peanut-specific immunoglobulin E (IgE) (a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEANUT ALLERGEN POWDER-DNFP

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a peanut allergy (ICD-10 Z91.010) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist or immunologist
   - Palforzia will be used in conjunction with a peanut-avoidance diet
   - Palforzia will NOT be used concurrently with a peanut-specific immunotherapy (e.g., Viaskin Peanut)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient completed a purposeful food challenge?

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient have a persistent peanut allergy and meet **ONE** of the following criteria?
   - The patient tested positive on a skin prick test with a wheal diameter of at least 3 mm within the past 24 months
   - The patient has had a peanut-specific immunoglobulin E (IgE) level of at least 0.35 kUA/L within the past 24 months

   If yes, **approve all of the following for 24 months by GPID or GPI-14 as follows:**
   - **300 mg powder packet/sachet: #1 per day.**
   - **All other strengths: No quantity limit.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a persistent peanut allergy and meet **ONE** of the following criteria?
   - The patient tested positive on a skin prick test with a wheal diameter of at least 8 mm within the past 24 months
   - The patient has had a peanut-specific immunoglobulin E (IgE) level of at least 14 kUA/L within the past 24 months

   If yes, **approve all of the following for 24 months by GPID or GPI-14 as follows:**
   - **300 mg powder packet/sachet: #1 per day.**
   - **All other strengths: No quantity limit.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PEANUT ALLERGEN POWDER-DNFP

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for renewal:

A. You have an allergy to peanuts
B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor) or immunologist (a type of immune system doctor)
C. Palforzia will be used together with a peanut-avoidance diet
D. Palforzia will NOT be used concurrently (at the same time) with peanut-specific immunotherapy (such as Viaskin Peanut)
E. You meet ONE of the following:
    1. If you have completed a purposeful food challenge (a type of test): you have a persistent peanut allergy based on a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 3 mm within the past 24 months, OR based on a peanut-specific immunoglobulin E (IgE) (a blood test that indicates an allergy to peanuts) level of at least 0.35 kUA/L within the past 24 months
    2. If you have NOT completed a purposeful food challenge (a type of test): you have a persistent peanut allergy based on a positive skin prick test (a skin test to check for peanut allergy) with a wheal diameter of at least 8 mm within the past 24 months, OR based on a peanut-specific immunoglobulin E (IgE) (a blood test that indicates an allergy to peanuts) level of at least 14 kUA/L within the past 24 months

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palforzia.

REFERENCES

Palforzia [Prescribing Information]. Lenoir, NC: Greer Laboratories, Inc.; September 2024.

Created: 02/20
Effective: 04/07/25 Client Approval: 03/25 P&T Approval: 07/20

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGAPTANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGAPTANIB SODIUM	MACUGEN	26805		GPI-10 (8665505030)	

GUIDELINES FOR USE

1. Is this medication prescribed by or given in consultation with an ophthalmologist and/or retina specialist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (AMD)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient receiving treatment in both eyes at this time?

   If yes, **approve for 12 months by HICL or GPI-10 for up to 18 syringes (2 syringes per 6 weeks).**
   If no, and a single eye is being treated, **approve for 12 months by HICL or GPI-10 for up to 9 syringes (1 syringe per 6 weeks).**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGAPTANIB (Macugen)** requires the following rule(s) be met for approval:
1. You have neovascular (wet) age-related macular degeneration (a chronic eye disorder that causes blurred vision or a blind spot in your visual field)
2. The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) and/or retina specialist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGAPTANIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Macugen.

REFERENCES

Macugen [Prescribing Information]. San Dimas, CA: Eyetech Inc.; July 2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20

Created: 05/14
Client Approval: 04/20

P&T Approval: 05/14

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGASPARGASE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGASPARGASE	ONCASPAR	08904		GPI-10 (2125006000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) **AND** meet the following criterion?
   - Oncaspar will be used as a component of a multi-agent chemotherapeutic regimen

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - Oncaspar will be used as a first-line therapy
   - The patient has a hypersensitivity to native forms of L-asparaginase

   If yes, **approve for 12 months by HICL or GPI-10 for #1 fill per 14 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGASPARGASE (Oncaspar)** requires the following rule(s) be met for approval:
   A. You have acute lymphoblastic leukemia (ALL: a type of blood cancer)
   B. Oncaspar will be used as a part of a chemotherapeutic treatment plan with multiple drugs
   C. You meet ONE of the following:
      1. Oncaspar will be used as a first-line therapy (drug used for initial treatment)
      2. You have a hypersensitivity to native forms of L-asparaginase (you are allergic to natural forms of a type of enzyme/protein)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ASPARAGINASE (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oncaspar.

REFERENCES

Oncaspar [Prescribing Information]. Boston, MA: Servier Pharmaceuticals LLC; March 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/15/24
Created: 03/24
Client Approval: 03/24
P&T Approval: 04/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGCETACOPLAN - INTRAOCULAR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGCETACOPLAN	SYFOVRE	48722		GPI-10 (8645406500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of geographic atrophy (GA) due to age-related macular degeneration (AMD) (ICD-10 Group H35.31)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.2mL per 25 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGCETACOPLAN - INTRAOCULAR (Syfovre)** requires the following rule(s) be met for approval:
   A. You have geographic atrophy (GA: an advanced type of eye disease) due to age-related macular degeneration (AMD: a type of eye disease)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Syfovre.

REFERENCES
Syfovre [Prescribing Information]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2023.

Created: 04/23
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGCETACOPLAN - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGCETACOPLAN	EMPAVELI	47380		GPI-10 (8580406500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent
   - Empaveli will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (e.g., Fabhalta [iptacopan]) or Factor D inhibitor therapy (e.g., Voydeya [danicopan])

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #200mL per 30 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of complement 3 glomerulopathy (C3G) (ICD-10 N00.A, N01.A, N02.A, N03.A, N04.A, N05.A, N06.A, N07.A, N00.6, N01.6, N02.6, N03.6, N04.6, N05.6, N06.6, N07.6) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a renal biopsy
   - The patient has a urine-protein creatine ratio (UPCR) of at least 1 g/g
   - The patient has an eGFR of at least 30mL/min/1.73m(2)
   - The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes
   - Empaveli will NOT be used concurrently with another complement inhibitor (e.g., Fabhalta [iptacopan]) for the same indication

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #160mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PEGCETACOPLAN - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGCETACOPLAN - SQ (Empaveli)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   2. Complement 3 glomerulopathy (C3G: a type of kidney disease) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN: a type of kidney disease)

B. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
   4. You will NOT use Empaveli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (such as Fabhalta [iptacopan]) or Factor D inhibitor therapy (such as Voydeya [danicopan])

C. If you have complement 3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis, approval also requires:
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   3. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
   4. You have a urine-protein creatine ratio (UPCR: a test that measures the amount of protein in urine) of at least 1g/g
   5. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30mL/min/1.73m(2)
   6. You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes
   7. You will NOT use Empaveli concurrently (at the same time) with another complement inhibitor (such as Fabhalta [iptacopan]) for the same indication

This is why your request is denied. Please work with your doctor to use a different medication or

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get us more information if it will allow us to approve this request.

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PEGCETACOPLAN - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline (baseline defined as patient condition post treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz])
   - Empaveli will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (e.g., Fabhalta [iptacopan]) or Factor D inhibitor therapy (e.g., Voydeya [danicopan])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #200mL per 30 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of complement 3 glomerulopathy (C3G) (ICD-10 N00.A, N01.A, N02.A, N03.A, N04.A, N05.A, N06.A, N07.A, N00.6, N01.6, N02.6, N03.6, N04.6, N05.6, N06.6, N07.6) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) and meet **ALL** of the following criteria?
   - The patient has had a reduction in proteinuria OR has improved or stable kidney function compared to baseline
   - Empaveli will NOT be used concurrently with another complement inhibitor (e.g., Fabhalta [iptacopan]) for the same indication

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #160mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGCETACOPLAN - SQ (Empaveli)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
      2. Complement 3 glomerulopathy (C3G: a type of kidney disease) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN: a type of kidney disease)

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

B. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
1. You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (baseline is defined as your condition after treatment with Soliris [eculizumab] or Ultomiris [ravulizumab-cwvz])
2. You will NOT use Empaveli concurrently (at the same time) with C5 complement inhibitor therapy (such as Ultomiris [ravulizumab-cwvz], Soliris [eculizumab], Piasky [crovalimab-akkz]), Factor B inhibitor therapy (such as Fabhalta [iptacopan]) or Factor D inhibitor therapy (such as Voydeya [danicopan])

C. If you have complement 3 glomerulopathy or primary immune-complex membranoproliferative glomerulonephritis, renewal also requires:
1. You have had a reduction (decrease) in proteinuria (high levels of protein in the urine) OR you have improved or stable kidney function compared to baseline (before treatment)
2. You will NOT use Empaveli concurrently (at the same time) with another complement inhibitor (such as Fabhalta [iptacopan]) for the same indication

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Empaveli.

REFERENCES
Empaveli [Prescribing Information]. Waltham, MA: Apellis Pharmaceuticals, Inc.; July 2025.

Created: 05/21
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM	NEULASTA, NEULASTA ONPRO	23255		GPI-10 (8240157000)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, continue to #3.
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) **AND** meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Neulasta **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to ONE of the following the preferred agents: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

   If yes, **approve all strengths of Neulasta for 12 months by GPID or GPI-14.**
   If no, continue to #4.

4. Is the request for Neulasta Onpro **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to the preferred agent: Udenyca Onbody (pegfilgrastim-cbqv)

   If yes, **approve Neulasta Onpro for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM (Neulasta, Neulasta Onpro)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You meet ONE of the following:
      a. You are requesting Neulasta AND you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)
      b. You are requesting Neulasta Onpro AND you have tried or have a contraindication to (harmful for you to use) the preferred medication: Udenyca Onbody (pegfilgrastim-cbqv)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You meet ONE of the following:
      a. You are requesting Neulasta AND you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)
      b. You are requesting Neulasta Onpro AND you have tried or have a contraindication to (harmful for you to use) the preferred medication: Udenyca Onbody (pegfilgrastim-cbqv)

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PEGFILGRASTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Neulasta.

REFERENCES

Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; August 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-APGF

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-APGF	NYVEPRIA	46612		GPI-10 (8240157002)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-APGF (Nyvepria)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
      2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

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PEGFILGRASTIM-APGF

GUIDELINES FOR USE (CONTINUED)

B. If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nyvepria and Neulasta.

REFERENCES
Nyvepria [Prescribing Information]. New York, NY: Pfizer; April 2021.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-BMEZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-BMEZ	ZIEXTENZO	46183		GPI-10 (8240157005)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   (NOTE: Enter a proactive PA for Fulphila for 12 months by HICL or GPI-10.)

   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) **AND** meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   (NOTE: Enter a proactive PA for Fulphila for 12 months by HICL or GPI-10.)

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-BMEZ (Ziextenzo)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
      2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

   B. If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
      1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
      2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

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PEGFILGRASTIM-BMEZ

GUIDELINES FOR USE (CONTINUED)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Ziextenzo and Neulasta.

REFERENCES
Ziextenzo [Prescribing Information]. Princeton, NJ: Sandoz Inc.; March 2021.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-CBQV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-CBQV	UDENYCA, UDENYCA ONBODY	45445		GPI-10 (8240157010)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, continue to #3.
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) **AND** meets the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for Udenyca **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

   If yes, **approve Udenyca for 12 months by GPID or GPI-14.**
   If no, continue to #4.

4. Is the request for Udenyca Onbody?

   If yes, **approve Udenyca Onbody for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEGFILGRASTIM-CBQV

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM - CBQV (Udenyca, Udenyca Onbody)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. If you are requesting Udenyca, approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. If you are requesting Udenyca, approval also requires you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Udenyca and Neulasta.

REFERENCES

Udenyca [Prescribing Information]. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-FPGK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-FPGK	STIMUFEND	48269		GPI-10 (8240157015)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-FPGK (Stimufend)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
      2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

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PEGFILGRASTIM-FPGK

GUIDELINES FOR USE (CONTINUED)

B. If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stimufend and Neulasta.

REFERENCES

Stimufend [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-JMDB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-JMDB	FULPHILA	45010		GPI-10 (8240157020)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-JMDB (Fulphila)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
      2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

   B. If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
      1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
      2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

   C. **If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires**:
      1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)

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PEGFILGRASTIM-JMDB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fulphila and Neulasta.

REFERENCES

Fulphila [Prescribing Information]. Cambridge, MA: Biocon Biologics Inc.; June 2023.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-PBBK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-PBBK	FYLNETRA	48035		GPI-10 (8240157060)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGFILGRASTIM-PBBK (Fylnetra)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
      2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

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PEGFILGRASTIM-PBBK

GUIDELINES FOR USE (CONTINUED)

B. If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

C. **If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires**:
1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Fylnetra and Neulasta.

REFERENCES
Fylnetra [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2022.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-UNNE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-UNNE	ARMLUPEG	51183		GPI-10 (8240157074)	

GUIDELINES FOR USE

1. Is the patient receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia and meets **ALL** of the following criteria?
   - The patient has a non-myeloid malignancy
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to ONE of the following the preferred agents: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Has the patient been acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient had a trial of or contraindication to ONE of the following the preferred agents: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline named **PEGFILGRASTIM-UNNE (Armlupeg)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are receiving myelosuppressive anti-cancer medications (medications that decrease bone marrow activity) associated with a clinically significant incidence of febrile neutropenia (a type of blood condition with fever)
   2. You have been acutely exposed to myelosuppressive doses (doses that decrease bone marrow activity) of radiation (hematopoietic subsyndrome of acute radiation syndrome [H-ARS]: an illness that happens after whole body radiation)

B. If you are receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia, approval also requires:
   1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following the preferred medications: Ziextenzo (pegfilgrastim-bmez) , Fulphila (pegfilgrastim-jmdb)

C. If you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following the preferred medications: Ziextenzo (pegfilgrastim-bmez), Fulphila (pegfilgrastim-jmdb)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Armlupeg and Neulasta.

REFERENCES

Armlupeg [Prescribing Information]. Naples, FL: Lupin Pharmaceuticals, Inc.; July 2026.
Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; August 2025.

Created: 09/26
Effective: 09/12/26 Client Approval: 09/26 DMC Approval: 09/09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGINTERFERON ALFA 2A OR 2B

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK	24035		GPI-10 (1235306005)	
PEGINTERFERON ALFA-2B	PEGINTRON		89387	GPI-10 (1235306010)	

GUIDELINES FOR USE

1. Is the request for the treatment of chronic hepatitis C virus infection (HCV) (ICD-10 B18.2)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for Pegasys?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have chronic hepatitis B (ICD-10 B18.0, B18.1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient 3 to 17 years of age and meet **ALL** of the following criteria?
   - The patient does NOT have cirrhosis
   - The patient has serum HBeAg-positive chronic hepatitis B
   - The patient has evidence of viral replication with elevated serum alanine aminotransferase (ALT)

   If yes, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
   If no, continue to #5.

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PEGINTERFERON ALFA 2A OR 2B

GUIDELINES FOR USE (CONTINUED)

5. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
   - The patient has serum HBeAg-positive or HBeAg-negative chronic hepatitis B
   - The patient has compensated liver disease with evidence of viral replication and liver inflammation

   If yes, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #4 per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys, PegIntron)** requires the following rule(s) be met for approval:
   A. You have chronic hepatitis B (a type of liver infection)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive condition), infectious disease specialist (a doctor who specializes in the treatment of infections), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   C. If you are 3 to 17 years of age, approval also requires:
      1. You do NOT have cirrhosis (liver damage)
      2. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)- positive chronic hepatitis B
      3. You have evidence of viral replication (virus is multiplying in the body) with elevated serum alanine aminotransferase (ALT: a type of liver enzyme test)
   D. If you are 18 years of age or older, approval also requires:
      1. Your blood test shows you have HBeAg (marker of active virus multiplying in the body)- positive or HBeAg-negative chronic hepatitis B
      2. You have compensated liver disease (a type of liver condition) with evidence of viral replication and liver inflammation

   Note: Pegasys and PegIntron will not be approved for the treatment of hepatitis C.

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGINTERFERON ALFA 2A OR 2B

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pegasys/PegIntron.

REFERENCES

Pegasys [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2021.
Pegintron [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., January 2019.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEG-INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGINTERFERON ALFA-2B	SYLATRON		29809 29812	GPI-10 (2170007520)	

GUIDELINES FOR USE

1. Is the patient currently taking the requested medication?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient received 5 years of therapy with Sylatron?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10.**

3. Does the patient have a diagnosis of melanoma with microscopic or gross nodal involvement (ICD-10 Group C43.9) within 84 days of definitive surgical resection?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEG-INTERFERON ALFA-2B (Sylatron)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You are currently taking Sylatron and have NOT received 5 years of treatment with Sylatron
      2. You have melanoma (skin cancer) with microscopic or gross nodal involvement (presence of cancer cells in the lymph nodes) within 84 days of definitive surgical resection (removal)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEG-INTERFERON ALFA-2B

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sylatron.

REFERENCES

Sylatron [Prescribing Information]. Whitehouse Station, NJ: Merck & Co.; August 2019.

Created: 05/11
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGLOTICASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGLOTICASE	KRYSTEXXA	37154		GPI-10 (6800005000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic gout (ICD-10 Group M1A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's disease is refractory to conventional therapy
   - The patient has a baseline serum uric acid levels of at least 8 mg/dL while on conventional gout medications (e.g., allopurinol)
   - The patient does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency
   - Krystexxa will NOT be used concurrently with other urate-lowering therapy (e.g., xanthine oxidase inhibitors, febuxostat, probenecid)
   - The patient had a trial of or contraindication to TWO conventional gout medications (e.g., allopurinol, probenecid) at a maximum tolerated dose for at least 3 months
   - Krystexxa will be co-administered with weekly oral methotrexate 15mg and folic acid, unless contraindicated

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have symptomatic gout as evidenced by **ONE** of the following criteria?
   - At least 3 or more gout flares in the previous 18 months
   - History of at least 1 gout tophus
   - Gouty arthritis

   If yes, **approve the requested strength for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **8mg/mL: #2mL per 28 days.**
   - **8mg/50mL: #100mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PEGLOTICASE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGLOTICASE (Krystexxa)** requires the following rules be met for approval:

A. You have chronic gout (a type of long-term joint condition)
B. You are 18 years of age or older
C. Your disease is refractory (did not respond) to conventional (standard) therapy
D. You had a baseline serum uric acid level (a type of lab test) of at least 8 mg/dL while on conventional (standard) gout medications (such as allopurinol)
E. You do not have glucose-6-phosphate dehydrogenase (G6PD) deficiency (a genetic disorder that affects red blood cells)
F. You will NOT use Krystexxa concurrently (at the same time) with other urate-lowering therapy (such as xanthine oxidase inhibitors, febuxostat, probenecid)
G. You have tried or have a contraindication to (harmful for you to use) TWO conventional (standard) gout medications (such as allopurinol, probenecid) at a maximum tolerated dose for at least 3 months
H. Krystexxa will be given with weekly oral methotrexate 15mg and folic acid, unless contraindicated (harmful for you to use)
I. You have symptomatic gout as shown by ONE of the following:
    1. At least 3 or more gout flares (episodes of pain or swelling associated with a type of joint condition) in the previous 18 months
    2. History of at least 1 gout tophus (uric acid crystallizes in joints like hands/feet)
    3. Gouty arthritis (severe pain and inflammation in joints due to gout)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEGLOTICASE

RENEWAL CRITERIA

1. Does the patient have sustained serum uric acid levels below 6 mg/dL?

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   8mg/mL: #2mL per 28 days.
   8mg/50mL: #100mL per 28 days.

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGLOTICASE (Krystexxa)** requires a sustained serum uric level (a type of lab test) below 6 mg/dL for renewal.

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Krystexxa.

REFERENCES

Krystexxa [Prescribing Information]. Dublin, Ireland: Horizon Therapeutics Ireland DAC; August 2025.

Created: 08/18
Effective: 10/13/25 Client Approval: 10/25 P&T Approval: 10/22

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGUNIGALSIDASE ALFA-IWXJ (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGUNIGALSIDASE ALFA-IWXJ	ELFABRIO	48913		GPI-10 (3090366010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
   - The patient is symptomatic OR has evidence of injury to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)
   - Elfabrio will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Galafold [migalastat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a female **AND** the patient meets the following criterion?
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the request for a male and the patient meets **ONE** of the following criteria?
   - The patient has an alpha galactosidase A (a-Gal-A) deficiency as indicated by an enzyme assay
   - The patient has a galactosidase alpha (GLA) gene mutation via genetic testing

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PEGUNIGALSIDASE ALFA-IWXJ (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGUNIGALSIDASE ALFA-IWXJ (Elfabrio)** requires the following rule(s) be met for approval:

A. You have Fabry disease (a rare genetic disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor), cardiologist (a type of heart doctor), or a doctor specializing in genetics or inherited metabolic disorders
D. You are symptomatic OR have evidence of injury to the kidney, heart, or central nervous system recognized by laboratory, histological (viewed by microscope), or imaging findings. Evidence of injury may include decreased glomerular filtration rate (GFR: a tool for evaluating kidney function) for age, persistent albuminuria (protein in urine), cerebral white matter lesions on brain MRI (magnetic resonance imaging: type of imaging lab), cardiac fibrosis (abnormal thickening of heart valves) on contrast cardiac MRI
E. You will NOT use Elfabrio concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Galafold [migalastat])
F. If you are a female, approval also requires:
    1. You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing
G. If you are a male, approval also requires ONE of the following:
    1. You do NOT have enough alpha galactosidase A (a-Gal-A: a type of protein) as indicated by an enzyme assay (a type of lab test)
    2. You have a galactosidase alpha (GLA) gene mutation (abnormal change in a type of gene) as shown by genetic testing

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGUNIGALSIDASE ALFA-IWXJ (NSA)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease (ICD-10 E75.21) **AND** meet the following criterion?
   - Elfabrio will NOT be used concurrently with another Fabry disease therapy (e.g., Fabrazyme [agalsidase beta], Galafold [migalastat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient demonstrated improvement, maintenance, or stabilization in **ONE** of the following while on therapy?
   - Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
   - Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
   - Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGUNIGALSIDASE ALFA-IWXJ (Elfabrio)** requires the following rule(s) be met for renewal:
   A. You have Fabry disease (a rare genetic disease)
   B. You will NOT use Elfabrio concurrently (at the same time) with another Fabry disease medication (such as Fabrazyme [agalsidase beta], Galafold [migalastat])
   C. You have demonstrated improvement, maintenance, or stabilization in ONE of the following while on therapy:
      1. Symptoms (such as pain, hypohidrosis [less sweating]/anhidrosis [no sweating], exercise intolerance, GI [gastrointestinal] symptoms, angiokeratomas [dark red-blue raised spots on the skin], abnormal cornea [a part of the eye], tinnitus [ringing in the ears]/hearing loss)
      2. Imaging such as brain/cardiac MRI [magnetic resonance imaging: type of imaging lab], DEXA [a type of bone scan], renal [kidney] ultrasound)
      3. Laboratory or histological (viewed by microscope) testing (such as GL-3 [globotriaosylceramide: a type of fat] in plasma/urine, renal biopsy [removal of cells or tissue from the body for examination])

   (Renewal denial text continued on next page)

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PEGUNIGALSIDASE ALFA-IWXJ (NSA)

RENEWAL CRITERIA

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elfabrio.

REFERENCES

Elfabrio [Prescribing Information]. Cary, NC: Chiesi USA, Inc.; May 2024.

Library	Commercial	NSA
Yes	No	Yes

Created: 08/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGVALIASE-PQPZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGVALIASE-PQPZ	PALYNZIQ	44944		GPI-10 (3090855040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of phenylketonuria (PKU) (ICD-10 E70.0) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a metabolic or genetic disease specialist
   - The patient follows a phenylalanine-restricted diet
   - The patient has uncontrolled blood phenylalanine (Phe) levels greater than 600 micromoles/L on existing management, as confirmed by a measurement in the last 30 days
   - Palynziq will NOT be used concurrently with another agent indicated for the treatment of phenylketonuria (PKU) (e.g., Kuvan [sapropterin], Sephience [sepiapterin])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2.5mg/0.5mL: #1mL per 7 days.**
   - **10mg/0.5mL: #0.5mL per day.**
   - **20mg/mL: #3mL per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rule(s) be met for approval:
   A. You have phenylketonuria (PKU: a type of genetic metabolic disorder)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or in consultation with a metabolic or genetic disease specialist (a doctor that treats metabolic or gene disorders)
   D. You follow a phenylalanine-restricted diet (a type of diet)
   E. You have uncontrolled blood phenylalanine (Phe) levels greater than 600 micromoles/L on your existing management, as confirmed by a measurement in the last 30 days
   F. You will NOT use Palynziq concurrently (at the same time) with another medication indicated for the treatment of phenylketonuria (PKU) (such as Kuvan [sapropterin], Sephience [sepiapterin])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGVALIASE-PQPZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of phenylketonuria (PKU) (ICD-10 E70.0) and meet **ALL** of the following criteria?
   - The patient has experienced a reduction in phenylalanine (Phe) levels by at least 20% compared to baseline or to a level below 600 micromoles/L
   - Palynziq will NOT be used concurrently with another agent indicated for the treatment of phenylketonuria (PKU) (e.g., Kuvan [sapropterin], Sephience [sepiapterin])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2.5mg/0.5mL: #1mL per 7 days.**
   - **10mg/0.5mL: #0.5mL per day.**
   - **20mg/mL: #3mL per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVALIASE-PQPZ (Palynziq)** requires the following rule(s) be met for renewal:
   A. You have phenylketonuria (PKU: a type of genetic metabolic disorder)
   B. Your phenylalanine (Phe) levels have decreased by at least 20% compared to baseline (before treatment) or to a level below 600 micromoles/L
   C. You will NOT use Palynziq concurrently (at the same time) with another medication indicated for the treatment of phenylketonuria (PKU) (such as Kuvan [sapropterin], Sephience [sepiapterin])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palynziq.

REFERENCES

Palynziq [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc.; February 2026.

Created: 08/18
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGVISOMANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGVISOMANT	SOMAVERT	25062		GPI-10 (3018006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient had an inadequate response to surgery or radiation OR surgery or radiation is not an option for this patient
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's serum insulin-like growth factor 1 (IGF-1) level (adjusted for the patient's age) is elevated or unequivocal with inadequate suppression of growth hormone after a glucose load

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Mycapssa, Sandostatin LAR Depot (octreotide acetate ER)
   - Somavert will be used concurrently with a somatostatin analog (e.g., Mycapssa, Sandostatin LAR Depot [octreotide acetate ER])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVISOMANT (Somavert)** requires the following rule(s) be met for approval:
   A. You have acromegaly (a type of hormone disorder)
   B. You had an inadequate response (did not work) to surgery or radiation, OR surgery or radiation is not an option for you
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)

   (Initial denial text continued on the next page)

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PEGVISOMANT

INITIAL CRITERIA (CONTINUED)

D. Your serum insulin-like growth factor 1 (IGF-1: a type of hormone) level (adjusted for your age) is elevated (higher than normal) or unequivocal with inadequate suppression (reduction) of growth hormone after a glucose load (a type of test used to diagnose acromegaly [a type of hormone disorder])
E. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Mycapssa, Sandostatin LAR Depot (octreotide acetate ER)
    2. You will use Somavert concurrently (at the same time) with a somatostatin analog (a type of medication such as Mycapssa, Sandostatin LAR Depot [octreotide acetate ER])

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PEGVISOMANT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acromegaly (ICD-10 E22.0) and meet **ALL** of the following criteria?
   - The patient has had a reduction, normalization, or maintenance of IGF-1 levels based on age and gender
   - The patient has shown improvement or has sustained remission of clinical symptoms of acromegaly

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGVISOMANT (Somavert)** requires the following rule(s) be met for renewal:
   A. You have acromegaly (a type of hormone disorder)
   B. You have had a reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
   C. You have shown improvement or have sustained remission (reduction or disappearance) of clinical symptoms of acromegaly (a type of hormone disorder)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Somavert.

REFERENCES

Somavert [Prescribing Information]. New York, NY: Pfizer Inc.; July 2023.

Created: 05/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGZILARGINASE-NBLN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGZILARGINASE-NBLN	LOARGYS	50171		GPI-10 (3090276000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Arginase 1 Deficiency (ARG1-D) (ICD-10 E72.21) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Loargys will be used in conjunction with dietary protein restriction
   - Therapy is prescribed by or in consultation with a metabolic specialist
   - The patient has a documented plasma arginine level of at least 250 umol/L

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGZILARGINASE-NBLN (Loargys)** requires the following rule(s) be met for approval:
   A. You have Arginase 1 Deficiency (ARG1-D: a rare metabolic disorder)
   B. You are 2 years of age or older
   C. Loargys will be used together with dietary protein restriction
   D. Therapy is prescribed by or in consultation with a metabolic specialist
   E. You have a documented plasma arginine level (a type of lab test) of at least 250 micromole/liter

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGZILARGINASE-NBLN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Arginase 1 Deficiency (ARG1-D) (ICD-10 E72.21) **AND** meet the following criterion?
   - The patient has shown improvement of symptoms or reduction of arginine levels

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGZILARGINASE-NBLN (Loargys)** requires the following rule(s) be met for renewal:
   A. You have Arginase 1 Deficiency (ARG1-D: a rare metabolic disorder)
   B. You have shown improvement of symptoms or reduction (decrease) of arginine levels (a type of lab test)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Loargys.

REFERENCES

Loargys [Prescribing Information]. Chicago, IL: Immedica Pharma US Inc.; February 2026.

Created: 06/26
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMBROLIZUMAB	KEYTRUDA	41369		GPI-10 (2135795300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   - Keytruda will NOT be used concurrently with a targeted therapy (i.e., BRAF inhibitors [e.g., Braftovi (encorafenib), Tafinlar (dabrafenib)], MEK inhibitors [e.g., Mekinist (trametinib)], and NTRK inhibitors [e.g., Vitrakvi (larotrectinib), Rozlytrek (entrectinib)])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Stage IIB, IIC, or III melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has undergone complete resection
   - Keytruda will be used as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic nonsquamous (e.g., adenocarcinoma, large cell carcinoma) non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - Keytruda will be used in combination with pemetrexed and platinum chemotherapy (e.g., cisplatin, carboplatin)
   - The patient does NOT have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - Keytruda will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) of at least 1%] as determined by an FDA-approved test
   - The patient does NOT have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has stage III NSCLC AND is not a candidate for surgical resection or definitive chemoradiation
   - The patient has metastatic NSCLC

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) of at least 1%] as determined by an FDA-approved test
   - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient does NOT have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
   - The patient has an anaplastic lymphoma kinase (ALK) genomic tumor aberration AND disease progression on or after ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])
   - The patient has an epidermal growth factor receptor (EGFR) genomic tumor aberration AND disease progression on or after EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have resectable (node positive or tumor is at least 4 cm) non-small cell lung cancer (NSCLC) (ICD-10 Group C34) **AND** meet the following criterion?
   - Keytruda will be used in combination with platinum-containing chemotherapy (e.g., cisplatin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery following prior use in combination with platinum-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #10.

10. Does the patient have a diagnosis of Stage IB (T2a is at least 4 cm), II, or IIIA non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be used as adjuvant treatment following resection and platinum-based chemotherapy (e.g., cisplatin, carboplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #11.

11. Does the patient have a diagnosis of unresectable advanced or metastatic malignant pleural mesothelioma (MPM) (ICD-10 C45.0) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be given in combination with pemetrexed and platinum chemotherapy (e.g., cisplatin, carboplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #12.

12. Does the patient have a diagnosis of head and neck squamous cell carcinoma (HNSCC) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32)?

    If yes, continue to #13.
    If no, continue to #17.

13. Is the cancer resectable and locally advanced, and the patient meets **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, continue to #14.
    If no, continue to #15.

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

14. Does the patient meet **ONE** of the following criteria?
    - Keytruda will be used as single-agent neoadjuvant treatment, and then continued as adjuvant treatment in combination with radiotherapy (RT)
    - Keytruda will be used as a single agent following its prior use both as single-agent neoadjuvant treatment and as adjuvant treatment in combination with RT

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

15. Is the cancer either metastatic or both unresectable and recurrent, and the patient meets **ONE** of the following criteria?
    - Keytruda will be given in combination with platinum and fluorouracil (FU)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #16.

16. Is the cancer recurrent or metastatic **AND** the patient meets the following criterion?
    - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

17. Does the patient have a diagnosis of classical Hodgkin lymphoma (cHL) (ICD-10 Group C81) and meet **ONE** of the following criteria?
    - The patient is 18 years of age or older AND has relapsed or refractory cHL
    - The patient has refractory cHL, or cHL that has relapsed after 2 or more prior lines of therapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #18.

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

18. Does the patient have a diagnosis of primary mediastinal large B-cell lymphoma (PMBCL) (ICD-10 Group C85.2) and meet **ONE** of the following criteria?
    - The patient has refractory PMBCL
    - The patient has relapsed after 2 or more prior lines of therapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #19.

19. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (ICD-10 Groups C66, C67, C68) and meet **ONE** of the following criteria?
    - Keytruda will be used in combination with enfortumab vedotin (Padcev) AND the patient is 18 years of age or older
    - The patient is not eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #20.

20. Does the patient have a diagnosis of bladder cancer (ICD-10 Group C67, D09.0)?

    If yes, continue to #21.
    If no, continue to #23.

21. Is the cancer muscle invasive (MIBC) and the patient meets **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be used in combination with enfortumab vedotin (Padcev) as neoadjuvant treatment, and then continued as adjuvant treatment after a cystectomy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #22.

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

22. Is the cancer non-muscle invasive (NMIBC) and the patient meets **ALL** of the following criteria?
    - The patient has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk cancer with carcinoma in situ (CIS)
    - The patient is ineligible for or has elected not to undergo a cystectomy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

23. Does the patient have a diagnosis of an unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
    - The patient's tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) as determined by an FDA-approved test
    - The patient has disease progression following prior treatment and has no satisfactory alternative treatment options

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #24.

24. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer (CRC) (ICD-10 C19) **AND** meet the following criterion?
    - The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #25.

25. Does the patient have a diagnosis of locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1) as determined by an FDA-approved test

    If yes, continue to #26.
    If no, continue to #27.

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

26. Does the patient meet **ONE** of the following criteria?
    - The cancer is HER2-positive, AND Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
    - The cancer is HER2-negative, AND Keytruda will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

27. Does the patient have a diagnosis of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma (ICD-10 C16.0; Group C15) **AND** meet the following criterion?
    - The tumor is not amenable to surgical resection or definitive chemoradiation

    If yes, continue to #28.
    If no, continue to #29.

28. Does the patient meet **ONE** of the following criteria?
    - Keytruda will be used in combination with platinum- and fluoropyrimidine-based chemotherapy AND the patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1)
    - Keytruda will be used after one or more prior lines of systemic therapy AND the patient has a tumor of squamous cell histology that expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

29. Does the patient have a diagnosis of cervical cancer (ICD-10 Group C53)?

    If yes, continue to #30.
    If no, continue to #33.

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

30. Is the cancer locally advanced and the patient meets **ALL** of the following criteria?
    - The cancer is FIGO 2014 Stage III-IVA
    - The cancer involves the lower third of the vagina, hydronephrosis/a non-functioning kidney, or has spread to adjacent pelvic organs
    - Keytruda will be used in combination with chemoradiotherapy (CRT)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #31.

31. Is the cancer persistent, recurrent, or metastatic and the patient meets **ALL** of the following criteria?
    - Keytruda will be used in combination with chemotherapy (e.g., paclitaxel, cisplatin, carboplatin)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #32.

32. Is the cancer recurrent or metastatic and the patient meets **ALL** of the following criteria?
    - The patient has disease progression on or after chemotherapy
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

33. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
    - The patient's cancer is secondary to hepatitis B
    - The patient has received prior systemic therapy (e.g., Nexavar [sorafenib], oxaliplatin) other than a PD-1/PD-L1-containing regimen (e.g., Opdivo [nivolumab])

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #34.

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

34. Does the patient have a diagnosis of locally advanced unresectable or metastatic biliary tract cancer (BTC) (ICD-10 Group C24) **AND** meet the following criterion?
    - Keytruda will be used in combination with gemcitabine and cisplatin

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #35.

35. Does the patient have a diagnosis of recurrent locally advanced or metastatic Merkel cell carcinoma (MCC) (ICD-10 Group C4A, C7B.1)?

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #36.

36. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be used in combination with Inlyta (axitinib) OR Lenvima (lenvatinib)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #37.

37. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - Keytruda will be used for adjuvant treatment
    - The patient is at intermediate-high or high risk of recurrence following a nephrectomy, or following a nephrectomy and resection of metastatic lesions

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #38.

38. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet ALL of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda will be used for adjuvant treatment
    - Keytruda will be used in combination with Welireg (belzutifan)
    - The patient has renal cell carcinoma with a clear cell component (ccRCC)
    - The patient is at intermediate-high or high risk of recurrence following a nephrectomy, or following a nephrectomy and resection of metastatic lesions

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #39.

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

39. Does the patient have a diagnosis of primary advanced or recurrent endometrial carcinoma (ICD-10 C54.1) **AND** meet the following criterion?
    - Keytruda will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #40.

40. Does the patient have a diagnosis of advanced endometrial carcinoma (ICD-10 C54.1) and meet **ALL** of the following criteria?
    - The patient has experienced disease progression following prior systemic therapy
    - The patient is not a candidate for curative surgery or radiation

    If yes, continue to #41.
    If no, continue to #43.

41. Does the patient meet **ALL** of the following criteria?
    - Keytruda will be used in combination with lenvatinib (Lenvima)
    - The patient's cancer is mismatch repair proficient (pMMR) as determined by an FDA-approved test, OR is not microsatellite instability-high (MSI-H)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #42.

42. Is the patient's cancer microsatellite instability-high (MSI-H) OR mismatch repair deficient (dMMR) as determined by an FDA-approved test?

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

43. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
    - The patient's tumor is tumor mutational burden-high (TMB-H) [at least 10 mutations/megabase (mut/Mb)] as determined by an FDA-approved test
    - The patient has disease progression following prior treatment and has no satisfactory alternative treatment options

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #44.

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

44. Does the patient have a diagnosis of recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC (ICD-10 C44.02, C44.42, C44.82, C44.92; Groups C44.12, C44.22, C44.32, C44.52, C44.62, C44.72) **AND** meet the following criterion?
    - The disease is not curable by surgery or radiation

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #45.

45. Does the patient have a diagnosis of high-risk early-stage triple-negative breast cancer (TNBC) (ICD-10 Group C50) **AND** meet the following criterion?
    - Keytruda will be used in combination with chemotherapy (e.g., carboplatin, paclitaxel, doxorubicin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery following prior use in combination with chemotherapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #46.

46. Does the patient have a diagnosis of unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) (ICD-10 Group C50) and meet **ALL** of the following criteria?
    - Keytruda will be used in combination with Trodelvy (sacituzumab govitecan-hziy)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10), as determined by an FDA-authorized test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #47.

47. Does the patient have a diagnosis of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (ICD-10 Group C50) and meet **ALL** of the following criteria?
    - Keytruda will be used in combination with chemotherapy (e.g., paclitaxel, gemcitabine, carboplatin)
    - The tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #48.

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GUIDELINES FOR USE (CONTINUED)

48. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (ICD-10 Groups C56, C57.0, C48, C79.6) and meet **ALL** the following criteria?
    - The patient is 18 years of age or older
    - The patient has platinum-resistant cancer
    - Keytruda will be used in combination with paclitaxel
    - The tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1) as determined by an FDA-approved test
    - The patient has received one or more prior systemic treatment regimens

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.

    DENIAL TEXT: Our guideline named **PEMBROLIZUMAB (Keytruda)** requires the following rule(s) be met for approval:
    A. You have ONE of the following:
        1. Unresectable or metastatic melanoma (type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
        2. Stage IIB, IIC, or III melanoma (type of skin cancer)
        3. Non-small cell lung cancer (type of lung cancer)
        4. Unresectable advanced or metastatic malignant pleural mesothelioma (a tumor of the tissue lining the lungs and chest wall that cannot be removed by surgery or has spread to other parts of the body)
        5. Head and neck squamous cell carcinoma (type of neck cancer)
        6. Classical Hodgkin lymphoma (type of immune system cancer)
        7. Primary mediastinal large B-cell lymphoma (type of immune system cancer)
        8. Locally advanced or metastatic urothelial carcinoma (type of urinary system cancer that has spread to other parts of the body)
        9. Bladder cancer
        10. Unresectable or metastatic solid tumor (type of cancer that cannot be removed by surgery or has spread to other parts of the body)
        11. Unresectable or metastatic colorectal cancer (CRC: type of colon or rectal cancer that cannot be removed by surgery or has spread to other parts of the body)
        12. Locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that cannot be surgically removed, has spread to nearby tissue or has spread to other parts of the body)
        13. Locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with an epicenter of 1 to 5 centimeters above the GEJ) carcinoma (a type of digestive system cancer that has spread to nearby tissue or to other parts of the body)
        14. Cervical cancer
        15. Hepatocellular carcinoma (liver cancer)

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

16. Locally advanced unresectable or metastatic biliary tract cancer (BTC) (type of bile duct cancer that cannot be removed with surgery or has spread to other parts of the body)
17. Recurrent locally advanced or metastatic Merkel cell carcinoma (MCC: type of skin cancer that has returned or has spread to other parts of the body)
18. Renal cell carcinoma (kidney cancer)
19. Endometrial carcinoma (type of cancer that starts in the uterus)
20. Recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma (cSCC: a type of skin cancer that has returned, or has spread to other parts of the body or to nearby tissue or lymph nodes)
21. High-risk early-stage triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors)
22. Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be surgically removed and has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
23. Locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be removed with surgery or has spread to other parts of the body)
24. Epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (types of reproductive system or abdomen cancers)

B. If you have unresectable or metastatic melanoma, approval also requires:
1. You will NOT use Keytruda concurrently (at the same time) with a targeted therapy (BRAF inhibitors [such as Braftovi (encorafenib), Tafinlar (dabrafenib)], MEK inhibitors [such as Mekinist (trametinib)], and NTRK inhibitors [such as Vitrakvi (larotrectinib), Rozlytrek (entrectinib)])

C. If you have Stage IIB, IIC, or III melanoma, approval also requires:
1. You are 12 years of age or older
2. You have undergone complete resection (completely removed by surgery)
3. Keytruda will be used as adjuvant (add-on) treatment

D. If you have metastatic nonsquamous non-small cell lung cancer, approval also requires:
1. Keytruda will be used in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)
2. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)

E. If you have metastatic squamous non-small cell lung cancer, approval also requires:
1. Keytruda will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

F. If you have non-small cell lung cancer, approval also requires:
1. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
2. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
3. You meet ONE of the following:
   a. You have stage III non-small cell lung cancer AND you are not a candidate for surgical resection (removal) or definitive chemoradiation (a type of treatment)
   b. You have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body)

G. If you have metastatic non-small cell lung cancer, approval also requires:
1. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
2. You experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
3. You meet ONE of the following:
   a. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
   b. You have an anaplastic lymphoma kinase (ALK) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after ALK-directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
   c. You have an epidermal growth factor receptor (EGFR) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

H. If you have resectable (node positive or tumor is at least 4 cm) non-small cell lung cancer, approval also requires:
1. Keytruda will be used in combination with platinum-containing chemotherapy (such as cisplatin) as neoadjuvant treatment (given before main treatment), OR as a single agent (not given in combination with chemotherapy) as adjuvant (add-on) treatment after surgery following prior use in combination with platinum-containing chemotherapy

I. If you have Stage IB (T2a is at least 4 cm), II, or IIIA non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda will be used as adjuvant (add-on) treatment following resection (removed by surgery) and platinum-based chemotherapy (such as cisplatin, carboplatin)

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

J. If you have unresectable advanced or metastatic malignant pleural mesothelioma, approval also requires:
1. You are 18 years of age or older
2. Keytruda will be given in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)

K. If you have head and neck squamous cell carcinoma, approval also requires ONE of the following:
1. Your cancer is resectable (able to be removed by surgery) and locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) and you meet ALL of the following:
   a. You are 18 years of age or older
   b. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
   c. Keytruda will be used as single-agent neoadjuvant treatment (given before main treatment) and then continued as adjuvant (add-on) treatment in combination with radiotherapy (RT: a type of cancer treatment), OR Keytruda will be used as a single agent following its prior use both as single-agent neoadjuvant treatment and as adjuvant treatment in combination with RT
2. Your cancer is either metastatic (has spread to other parts of the body) or both unresectable (unable to remove by surgery) and recurrent (has returned), and you meet ONE of the following:
   a. Keytruda will be given in combination with platinum and fluorouracil (FU)
   b. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
3. Your cancer is recurrent (has returned) or metastatic (has spread to other parts of the body); AND you experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

L. If you have classical Hodgkin lymphoma, approval also requires ONE of the following:
1. You are 18 years of age or older AND have relapsed (disease has returned) or refractory (disease is resistant to treatment) classical Hodgkin lymphoma
2. You have refractory (disease is resistant to treatment) classical Hodgkin lymphoma or classical Hodgkin lymphoma that has relapsed (disease has returned) after 2 or more prior lines of therapy

M. If you have primary mediastinal large B-cell lymphoma, approval also requires ONE of the following:
1. You have refractory primary mediastinal large B-cell lymphoma (type of immune system cancer that is resistant to treatment)
2. You have relapsed (disease has returned) after 2 or more prior lines of therapy

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

N. If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:
1. Keytruda will be used in combination with enfortumab vedotin (Padcev), AND you are 18 years of age or older
2. You are not eligible for any platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
3. You have disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
4. You have disease progression (worsening) within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

O. If you have bladder cancer, approval also requires ONE of the following:
1. You have muscle invasive bladder cancer (MIBC: bladder cancer that has grown into the muscle wall); AND you are 18 years of age or older; AND Keytruda will be used in combination with enfortumab vedotin (Padcev) as neoadjuvant treatment (given before main treatment), and then continued as adjuvant (add-on) treatment after a cystectomy (surgery to remove part or all of the urinary bladder)
2. You have Bacillus Calmette-Guerin (BCG: a type of anti-cancer treatment)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (a type of early-stage bladder cancer); AND you are not eligible for or have chosen not to undergo a cystectomy (surgery to remove part or all of the urinary bladder)

P. If you have an unresectable or metastatic solid tumor, approval also requires:
1. You meet ONE of the following:
   a. Your tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities), as determined by a Food and Drug Administration (FDA)-approved test
   b. Your tumor is tumor mutational burden-high (TMB-H: high number of changes found in the genes of the cancer cells) [at least 10 mutations/megabase], as determined by a Food and Drug Administration (FDA)-approved test
2. Your disease has progressed (worsened) following prior treatment, and you have no alternative treatment options

Q. If you have unresectable or metastatic colorectal cancer, approval also requires:
1. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities) as determined by an FDA-approved test

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

R. If you have locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
3. You meet ONE of the following:
   a. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-POSITIVE, and Keytruda will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
   b. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-NEGATIVE, and Keytruda will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

S. If you have locally advanced or metastatic esophageal or gastroesophageal junction carcinoma, approval also requires:
1. Your tumor is not amenable (responsive) to surgical resection (removal) or definitive chemoradiation (a type of treatment)
2. You meet ONE of the following:
   a. Keytruda will be used in combination with platinum- and fluoropyrimidine-based chemotherapy; AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1)
   b. Keytruda will be used after one or more prior lines of systemic therapy; AND you have a tumor of squamous cell histology (cancer from flat surface-lining cells) that expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-approved test

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GUIDELINES FOR USE (CONTINUED)

T. If you have cervical cancer, approval also requires ONE of the following:
1. Your cancer is locally advanced, your cancer is FIGO 2014 Stage III-IVA (a way to classify the size and spread of the cancer) and involves the lower third of the vagina, hydronephrosis (swelling of kidney)/a non-functioning kidney, or has spread to adjacent (nearby) pelvic organs; AND Keytruda will be used in combination with chemoradiotherapy (CRT: a type of therapy to treat cancer)
2. You have persistent, recurrent, or metastatic cancer (cancer that does not go away, has returned, or has spread to other parts of the body); AND Keytruda will be used in combination with chemotherapy (such as paclitaxel, cisplatin, carboplatin); AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
3. You have recurrent or metastatic cancer (cancer that has returned or has spread to other parts of the body); AND you have experienced disease progression (worsening) on or after chemotherapy; AND your tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test

U. If you have hepatocellular carcinoma, approval also requires:
1. Your cancer is caused by hepatitis B (a type of liver infection)
2. You have received prior systemic therapy (such as Nexavar [sorafenib], oxaliplatin) other than a PD-1/PD-L1-containing regimen (such as Opdivo [nivolumab])

V. If you have locally advanced unresectable or metastatic biliary tract cancer, approval also requires:
1. Keytruda will be used in combination with gemcitabine and cisplatin

W. If you have renal cell carcinoma, approval also requires ONE of the following:
1. You have advanced renal cell carcinoma; you are 18 years of age or older; AND Keytruda will be used in combination with Inlyta (axitinib) OR Lenvima (lenvatinib)
2. Keytruda will be used as adjuvant (add-on) treatment; AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)
3. You are 18 years of age or older; AND Keytruda will be used in combination with Welireg (belzutifan), Keytruda will be used as adjuvant (add-on) treatment; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer), AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

X. If you have primary advanced or recurrent endometrial carcinoma, approval also requires:
1. Keytruda will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

Y. If you have advanced endometrial carcinoma, approval also requires:
1. You have experienced disease progression (worsening) following prior systemic therapy (treatment that affects the entire body)
2. You are not a candidate for curative surgery or radiation
3. You meet ONE of the following:
   a. You will use Keytruda in combination with lenvatinib (Lenvima), AND your cancer is mismatch repair proficient (pMMR) as determined by a Food and Drug Administration (FDA)-approved test OR is NOT microsatellite instability-high (MSI-H) (characteristics that help determine the type of cancer and what treatment options there are for it)
   b. Your cancer is microsatellite instability-high (MSI-H) OR mismatch repair deficient (dMMR) (types of genetic abnormalities), as determined by a Food and Drug Administration (FDA)-approved test

Z. If you have recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma, approval also requires:
1. Your disease is not curable by surgery or radiation

AA. **If you have high-risk early-stage triple-negative breast cancer, approval also requires:**
1. Keytruda will be used in combination with chemotherapy (such as carboplatin, paclitaxel, doxorubicin) as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant (add-on) treatment after surgery following prior use in combination with chemotherapy

BB. **If you have unresectable locally advanced or metastatic triple-negative breast cancer, approval also requires:**
1. Keytruda will be used in combination with Trodelvy (sacituzumab govitecan-hziy)
2. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-authorized test

CC. **If you have locally recurrent unresectable or metastatic triple-negative breast cancer, approval also requires:**
1. Keytruda will be used in combination with chemotherapy (such as paclitaxel, gemcitabine, carboplatin)
2. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-approved test

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PEMBROLIZUMAB

GUIDELINES FOR USE (CONTINUED)

DD. **If you have epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, approval also requires:**
1. You are 18 years of age or older
2. You have platinum-resistant cancer (cancer that no longer responds to a type of treatment)
3. Keytruda will be used in combination with paclitaxel
4. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
5. You have received one or more prior systemic treatment regimens (treatment that affects the entire body)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Keytruda.

REFERENCES

Keytruda [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; July 2026.

Created: 09/14
Effective: 07/29/26 Client Approval: 07/26 DMC Approval: 07/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMBROLIZUM-BERAHYALURON-PMPH	KEYTRUDA QLEX	50902		GPI-10 (2199000253)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Stage IIB, IIC, or III melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has undergone complete resection
   - Keytruda Qlex will be used as adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic nonsquamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Keytruda Qlex will be used in combination with pemetrexed and platinum chemotherapy (e.g., cisplatin, carboplatin)
   - The patient does NOT have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Keytruda Qlex will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) of at least 1%] as determined by an FDA-approved test
   - The patient does NOT have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has stage III NSCLC AND is not a candidate for surgical resection or definitive chemoradiation
   - The patient has metastatic NSCLC

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) of at least 1%] as determined by an FDA-approved test
   - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, continue to #8.
   If no, continue to #9.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

8. Does the patient meet **ONE** of the following criteria?
   - The patient does NOT have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
   - The patient has an anaplastic lymphoma kinase (ALK) genomic tumor aberration AND disease progression on or after ALK-directed therapy (e.g., Xalkori [crizotinib], Zykadia [ceritinib])
   - The patient has an epidermal growth factor receptor (EGFR) genomic tumor aberration AND disease progression on or after EGFR-directed therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have resectable (node positive or tumor is at least 4 cm) non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Keytruda Qlex will be used in combination with platinum-containing chemotherapy (e.g., cisplatin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery following prior use in combination with platinum-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #10.

10. Does the patient have a diagnosis of Stage IB (T2a is at least 4 cm), II, or IIIA non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used as adjuvant treatment following resection and platinum-based chemotherapy (e.g., cisplatin, carboplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #11.

11. Does the patient have a diagnosis of unresectable advanced or metastatic malignant pleural mesothelioma (MPM) (ICD-10 C45.0) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with pemetrexed and platinum chemotherapy (e.g., cisplatin, carboplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #12.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

12. Does the patient have a diagnosis of head and neck squamous cell carcinoma (HNSCC) (ICD-10 Groups C44.42, C76.0, C00, C06, C09, C10, C32) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #13.
    If no, continue to #17.

13. Is the cancer resectable and locally advanced **AND** the patient meets the following criterion?
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, continue to #14.
    If no, continue to #15.

14. Does the patient meet **ONE** of the following criteria?
    - Keytruda Qlex will be used as single-agent neoadjuvant treatment, and then continued as adjuvant treatment in combination with radiotherapy (RT)
    - Keytruda Qlex will be used as a single agent following its prior use both as single-agent neoadjuvant treatment and as adjuvant treatment in combination with RT

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

15. Is the cancer either metastatic or both unresectable and recurrent, and the patient meets **ONE** of the following criteria?
    - Keytruda Qlex will be used in combination with platinum and fluorouracil (FU)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #16.

16. Is the cancer recurrent or metastatic **AND** the patient meets the following criterion?
    - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

17. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (ICD-10 Groups C66, C67, C68) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #18.
    If no, continue to #19.

18. Does the patient meet **ONE** of the following criteria?
    - Keytruda Qlex will be used in combination with enfortumab vedotin (Padcev)
    - The patient is not eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression on or following treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
    - The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

19. Does the patient have a diagnosis of bladder cancer (ICD-10 Group C67, D09.0) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #20.
    If no, continue to #22.

20. Is the cancer muscle invasive (MIBC) **AND** the patient meets the following criterion?
    - Keytruda Qlex will be used in combination with enfortumab vedotin (Padcev) as neoadjuvant treatment, and then continued as adjuvant treatment after a cystectomy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #21.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

21. Is the cancer non-muscle invasive (NMIBC) and the patient meets **ALL** of the following criteria?
    - The patient has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk cancer with carcinoma in situ (CIS)
    - The patient is ineligible for or has elected not to undergo a cystectomy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

22. Does the patient have a diagnosis of an unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
    - The patient is 12 years of age or older
    - The patient's tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) as determined by an FDA-approved test
    - The patient has disease progression following prior treatment and has no satisfactory alternative treatment options

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #23.

23. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer (CRC) (ICD-10 C19) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #24.

24. Does the patient have a diagnosis of locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1) as determined by an FDA-approved test

    If yes, continue to #25.
    If no, continue to #26.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

25. Does the patient meet **ONE** of the following criteria?
    - The cancer is HER2-positive, AND Keytruda Qlex will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
    - The cancer is HER2-negative, AND Keytruda Qlex will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

26. Does the patient have a diagnosis of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma (ICD-10 C16.0; Group C15) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The tumor is not amenable to surgical resection or definitive chemoradiation

    If yes, continue to #27.
    If no, continue to #28.

27. Does the patient meet **ONE** of the following criteria?
    - Keytruda Qlex will be used in combination with platinum- and fluoropyrimidine-based chemotherapy AND the patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1) as determined by an FDA-authorized test
    - Keytruda Qlex will be used after one or more prior lines of systemic therapy AND the patient has a tumor of squamous cell histology that expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10) as determined by an FDA-authorized test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

28. Does the patient have a diagnosis of cervical cancer (ICD-10 Group C53) **AND** meet the following criterion?
    - The patient is 18 years of age or older

    If yes, continue to #29.
    If no, continue to #32.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

29. Is the cancer locally advanced and the patient meets **ALL** of the following criteria?
    - Keytruda Qlex will be used in combination with chemoradiotherapy (CRT)
    - The cancer involves the lower third of the vagina, hydronephrosis/a non-functioning kidney, or has spread to adjacent pelvic organs (FIGO 2014 Stage III-IVA)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #30.

30. Is the cancer persistent, recurrent, or metastatic and the patient meets **ALL** of the following criteria?
    - Keytruda Qlex will be used in combination with chemotherapy (e.g., paclitaxel, cisplatin, carboplatin)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #31.

31. Is the cancer recurrent or metastatic and the patient meets **ALL** of the following criteria?
    - The patient has disease progression on or after chemotherapy
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 1] as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

32. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient's cancer is secondary to hepatitis B
    - The patient has received prior systemic therapy (e.g., Nexavar [sorafenib], oxaliplatin) other than a PD-1/PD-L1-containing regimen (e.g., Opdivo [nivolumab])

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #33.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

33. Does the patient have a diagnosis of locally advanced unresectable or metastatic biliary tract cancer (BTC) (ICD-10 Group C24) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with gemcitabine and cisplatin

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #34.

34. Does the patient have a diagnosis of recurrent locally advanced or metastatic Merkel cell carcinoma (MCC) (ICD-10 Group C4A, C7B.1) **AND** meet the following criterion?
    - The patient is 12 years of age or older

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #35.

35. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with Inlyta (axitinib) OR Lenvima (lenvatinib)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #36.

36. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used for adjuvant treatment
    - The patient is at intermediate-high or high risk of recurrence following a nephrectomy, or following a nephrectomy and resection of metastatic lesions

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #37.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

37. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used for adjuvant treatment
    - Keytruda Qlex will be used in combination with Welireg (belzutifan)
    - The patient has renal cell carcinoma with a clear cell component (ccRCC)
    - The patient is at intermediate-high or high risk of recurrence following a nephrectomy, or following a nephrectomy and resection of metastatic lesions

38. Does the patient have a diagnosis of primary advanced or recurrent endometrial carcinoma (ICD-10 C54.1) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with carboplatin and paclitaxel, OR as a single agent after prior use in combination with carboplatin and paclitaxel

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #39.

39. Does the patient have a diagnosis of advanced endometrial carcinoma (ICD-10 C54.1) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has experienced disease progression following prior systemic therapy
    - The patient is not a candidate for curative surgery or radiation

    If yes, continue to #40.
    If no, continue to #42.

40. Does the patient meet **ALL** of the following criteria?
    - Keytruda Qlex will be used in combination with lenvatinib (Lenvima)
    - The patient's cancer is mismatch repair proficient (pMMR) OR not microsatellite instability-high (MSI-H) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #41.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

41. Is the patient's cancer microsatellite instability-high (MSI-H) OR mismatch repair deficient (dMMR) as determined by an FDA-approved test?

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

42. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
    - The patient is 12 years of age or older
    - The patient's tumor is tumor mutational burden-high (TMB-H) [at least 10 mutations/megabase (mut/Mb)] as determined by an FDA-approved test
    - The patient has disease progression following prior treatment and has no satisfactory alternative treatment options

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #43.

43. Does the patient have a diagnosis of recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC (ICD-10 C44.02, C44.42, C44.82, C44.92; Groups C44.12, C44.22, C44.32, C44.52, C44.62, C44.72) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The disease is not curable by surgery or radiation

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #44.

44. Does the patient have a diagnosis of high-risk early-stage triple-negative breast cancer (TNBC) (ICD-10 Group C50) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with chemotherapy (e.g., carboplatin, paclitaxel, doxorubicin) as neoadjuvant treatment, OR as a single agent as adjuvant treatment after surgery following prior use in combination with chemotherapy

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #45.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

45. Does the patient have a diagnosis of unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) (ICD-10 Group C50) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with Trodelvy (sacituzumab govitecan-hziy)
    - The patient's tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10), as determined by an FDA-authorized test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #46.

46. Does the patient have a diagnosis of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (ICD-10 Group C50) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Keytruda Qlex will be used in combination with chemotherapy (e.g., paclitaxel, gemcitabine, carboplatin)
    - The tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 10) as determined by an FDA-approved test

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #47.

47. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (ICD-10 Groups C56, C57.0, C48, C79.6) and meet **ALL** the following criteria?
    - The patient is 18 years of age or older
    - The patient has platinum-resistant cancer
    - Keytruda Qlex will be used in combination with paclitaxel
    - The tumor expresses programmed death-ligand 1 (PD-L1) (Combined Positive Score [CPS] of at least 1) as determined by an FDA-approved test
    - The patient has received one or more prior systemic treatment regimens

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT:

Our guideline named **PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH (Keytruda Qlex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
   2. Stage IIB, IIC, or III melanoma (type of skin cancer)
   3. Non-small cell lung cancer (type of lung cancer)
   4. Unresectable advanced or metastatic malignant pleural mesothelioma (a tumor of the tissue lining the lungs and chest wall that cannot be removed by surgery or has spread to other parts of the body)
   5. Head and neck squamous cell carcinoma (type of neck cancer)
   6. Locally advanced or metastatic urothelial carcinoma (type of urinary system cancer that has spread to other parts of the body)
   7. Bladder cancer
   8. Unresectable or metastatic solid tumor (type of cancer that cannot be removed by surgery or has spread to other parts of the body)
   9. Unresectable or metastatic colorectal cancer (CRC: type of colon or rectal cancer that cannot be removed by surgery or has spread to other parts of the body)
   10. Locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that cannot be surgically removed, has spread to nearby tissue or has spread to other parts of the body)
   11. Locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (tumors with an epicenter of 1 to 5 centimeters above the GEJ) carcinoma (a type of digestive system cancer that has spread to nearby tissue or to other parts of the body)
   12. Cervical cancer
   13. Hepatocellular carcinoma (liver cancer)
   14. Locally advanced unresectable or metastatic biliary tract cancer (BTC) (type of bile duct cancer that cannot be removed with surgery or has spread to other parts of the body)
   15. Recurrent locally advanced or metastatic Merkel cell carcinoma (MCC: type of skin cancer that has returned or has spread to other parts of the body)
   16. Renal cell carcinoma (kidney cancer)
   17. Endometrial carcinoma (type of cancer that starts in the uterus)
   18. Recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma (cSCC: a type of skin cancer that has returned, or has spread to other parts of the body or to nearby tissue or lymph nodes)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

19. High-risk early-stage triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors)
20. Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be surgically removed and has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
21. Locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be removed with surgery or has spread to other parts of the body)
22. Epithelial ovarian, fallopian tube, or primary peritoneal carcinoma (types of reproductive system or abdomen cancers)

B. If you have unresectable or metastatic melanoma, approval also requires:
1. You are 18 years of age or older

C. If you have Stage IIB, IIC, or III melanoma, approval also requires:
1. You are 12 years of age or older
2. You have undergone complete resection (completely removed by surgery)
3. Keytruda Qlex will be used as adjuvant (add-on) treatment

D. If you have metastatic nonsquamous non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)
3. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)

E. If you have metastatic squamous non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with carboplatin and either paclitaxel or paclitaxel protein-bound

F. If you have non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)- approved test
3. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
4. You meet ONE of the following:
   a. You have stage III non-small cell lung cancer AND you are not a candidate for surgical resection (removal) or definitive chemoradiation (a type of treatment)
   b. You have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

G. If you have metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Tumor Proportion Score (TPS) of at least 1%] as determined by a Food and Drug Administration (FDA)-approved test
3. You experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
4. You meet ONE of the following:
   a. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
   b. You have an anaplastic lymphoma kinase (ALK) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after ALK- directed therapy (such as Xalkori [crizotinib], Zykadia [ceritinib])
   c. You have an epidermal growth factor receptor (EGFR) genomic tumor aberration (type of gene mutation) AND experienced disease progression (worsening) on or after EGFR-directed therapy (such as Tarceva [erlotinib], Iressa [gefitinib], Gilotrif [afatinib])

H. If you have resectable (node positive or tumor is at least 4 cm) non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with platinum-containing chemotherapy (such as cisplatin) as neoadjuvant treatment (given before main treatment), OR as a single agent (not given in combination with chemotherapy) as adjuvant (add-on) treatment after surgery following prior use in combination with platinum-containing chemotherapy

I. If you have Stage IB (T2a is at least 4 cm), II, or IIIA non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used as adjuvant (add-on) treatment following resection (removed by surgery) and platinum-based chemotherapy (such as cisplatin, carboplatin)

J. If you have unresectable advanced or metastatic malignant pleural mesothelioma, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be given in combination with pemetrexed and platinum chemotherapy (such as cisplatin, carboplatin)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

K. If you have head and neck squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your cancer is resectable (able to be removed by surgery) and locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) and you meet ALL of the following:
      i. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
      ii. Keytruda Qlex will be used as single-agent neoadjuvant treatment (given before main treatment) and then continued as adjuvant (add-on) treatment in combination with radiotherapy (RT: a type of cancer treatment), OR Keytruda will be used as a single agent following its prior use both as single-agent neoadjuvant treatment and as adjuvant treatment in combination with RT
   b. Your cancer is either metastatic (has spread to other parts of the body) or both unresectable (unable to remove by surgery) and recurrent (has returned), and you meet ONE of the following:
      i. Keytruda Qlex will be used in combination with platinum and fluorouracil (FU)
      ii. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
   c. Your cancer is recurrent (has returned) or metastatic (has spread to other parts of the body); AND you experienced disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

L. If you have locally advanced or metastatic urothelial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Keytruda Qlex will be used in combination with enfortumab vedotin (Padcev)
   b. You are not eligible for any platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   c. You have disease progression (worsening) on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   d. You have disease progression (worsening) within 12 months of neoadjuvant (given before main treatment) or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

M. If you have bladder cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have muscle invasive bladder cancer (MIBC: bladder cancer that has grown into the muscle wall); AND Keytruda Qlex will be used in combination with enfortumab vedotin (Padcev) as neoadjuvant treatment (given before main treatment), and then continued as adjuvant (add-on) treatment after a cystectomy (surgery to remove part or all of the urinary bladder)
   b. You have Bacillus Calmette-Guerin (BCG: a type of anti-cancer treatment)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (a type of early-stage bladder cancer); AND you are not eligible for or have chosen not to undergo a cystectomy (surgery to remove part or all of the urinary bladder)

N. If you have an unresectable or metastatic solid tumor, approval also requires:
1. You are 12 years of age or older
2. You meet ONE of the following:
   a. Your tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities), as determined by a Food and Drug Administration (FDA)-approved test
   b. Your tumor is tumor mutational burden-high (TMB-H: high number of changes found in the genes of the cancer cells) [at least 10 mutations/megabase], as determined by a Food and Drug Administration (FDA)-approved test
3. Your disease has progressed (worsened) following prior treatment, and you have no alternative treatment options

O. If you have unresectable or metastatic colorectal cancer, approval also requires:
1. You are 18 years of age or older
2. Your cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) (types of genetic abnormalities) as determined by a Food and Drug Administration (FDA)-approved test

(Denial text continued on next page)

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

P. If you have locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You are 18 years of age or older
2. Your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
3. You meet ONE of the following:
   a. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-POSITIVE, and Keytruda Qlex will be used in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
   b. Your cancer is human epidermal growth factor receptor 2 (HER2: type of protein that promotes cancer cells)-NEGATIVE, and Keytruda Qlex will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

Q. If you have locally advanced or metastatic esophageal or gastroesophageal junction carcinoma, approval also requires:
1. You are 18 years of age or older
2. Your tumor is not amenable (responsive) to surgical resection (removal) or definitive chemoradiation (a type of treatment)
3. You meet ONE of the following:
   a. Keytruda Qlex will be used in combination with platinum- and fluoropyrimidine-based chemotherapy; AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-authorized test
   b. Keytruda Qlex will be used after one or more prior lines of systemic therapy; AND you have a tumor of squamous cell histology (cancer from flat surface-lining cells) that expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-authorized test

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GUIDELINES FOR USE (CONTINUED)

R. If you have cervical cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have locally advanced cancer (cancer that has spread from where it started to nearby tissue or lymph nodes); AND Keytruda Qlex will be used in combination with chemoradiotherapy (CRT: a type of therapy to treat cancer); AND your cancer involves the lower third of the vagina, hydronephrosis (swelling of kidney)/a non-functioning kidney, or has spread to adjacent (nearby) pelvic organs (FIGO 2014 Stage III-IVA: a way to classify the size and spread of the cancer)
   b. You have persistent, recurrent, or metastatic cancer (cancer that does not go away, has returned, or has spread to other parts of the body); AND Keytruda Qlex will be used in combination with chemotherapy (such as paclitaxel, cisplatin, carboplatin); AND your tumor expresses programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
   c. You have recurrent (has returned) or metastatic (has spread to other parts of the body) cancer; AND you have experienced disease progression (worsening) on or after chemotherapy; AND your tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test

S. If you have hepatocellular carcinoma, approval also requires:
1. You are 18 years of age or older
2. Your cancer is caused by hepatitis B (a type of liver infection)
3. You have received prior systemic therapy (such as Nexavar [sorafenib], oxaliplatin) other than a PD-1/PD-L1-containing regimen (such as Opdivo [nivolumab])

T. If you have locally advanced unresectable or metastatic biliary tract cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with gemcitabine and cisplatin

U. If you have recurrent locally advanced or metastatic Merkel cell carcinoma, approval also requires:
1. You are 12 years of age or older

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

V. If you have renal cell carcinoma, approval also requires ONE of the following:
1. You have advanced renal cell carcinoma; you are 18 years of age or older; AND Keytruda Qlex will be used in combination with Inlyta (axitinib) OR Lenvima (lenvatinib)
2. You are 18 years of age or older; Keytruda Qlex will be used as adjuvant (add-on) treatment; AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)
3. You are 18 years of age or older; AND Keytruda Qlex will be used in combination with Welireg (belzutifan), Keytruda Qlex will be used as adjuvant (add-on) treatment; AND you have renal cell carcinoma with a clear cell component (ccRCC: a type of kidney cancer), AND your cancer is at intermediate-high or high risk of recurrence (returning) following a nephrectomy (surgical removal of the kidney), or following a nephrectomy and resection (surgical removal) of metastatic lesions (abnormal area of tissue)

W. If you have primary advanced or recurrent endometrial carcinoma, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel

X. If you have advanced endometrial carcinoma, approval also requires:
1. You are 18 years of age or older
2. You have experienced disease progression (worsening) following prior systemic therapy (treatment that affects the entire body)
3. You are not a candidate for curative surgery or radiation
4. You meet ONE of the following:
   a. You will use Keytruda Qlex in combination with lenvatinib (Lenvima), AND your cancer is mismatch repair proficient (pMMR) OR not microsatellite instability-high (MSI-H) (characteristics that help determine the type of cancer and what treatment options there are for it) as determined by a Food and Drug Administration (FDA)- approved test
   b. Your cancer is microsatellite instability-high (MSI-H) OR mismatch repair deficient (dMMR) (types of genetic abnormalities) as determined by a Food and Drug Administration (FDA)-approved test

Y. If you have recurrent or metastatic OR locally advanced cutaneous squamous cell carcinoma, approval also requires:
1. You are 18 years of age or older
2. Your disease is not curable by surgery or radiation

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PEMBROLIZUMAB-BERAHYALURONIDASE ALFA-PMPH

GUIDELINES FOR USE (CONTINUED)

Z. If you have high-risk early-stage triple-negative breast cancer, approval also requires:
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with chemotherapy (such as carboplatin, paclitaxel, doxorubicin) as neoadjuvant treatment (given before main treatment), OR as a single agent as adjuvant (add-on) treatment after surgery following prior use in combination with chemotherapy

AA. **If you have unresectable locally advanced or metastatic triple-negative breast cancer, approval also requires:**
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with Trodelvy (sacituzumab govitecan-hziy)
3. Your tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10), as determined by a Food and Drug (FDA)- authorized test

BB. **If you have locally recurrent unresectable or metastatic triple-negative breast cancer, approval also requires:**
1. You are 18 years of age or older
2. Keytruda Qlex will be used in combination with chemotherapy (such as paclitaxel, gemcitabine, carboplatin)
3. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 10) as determined by a Food and Drug Administration (FDA)-approved test

CC. **If you have epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, approval also requires:**
1. You are 18 years of age or older
2. You have platinum-resistant cancer (cancer that no longer responds to a type of treatment)
3. Keytruda Qlex will be used in combination with paclitaxel
4. The tumor has programmed death-ligand 1 (PD-L1: a type of protein) (Combined Positive Score [CPS] of at least 1) as determined by a Food and Drug Administration (FDA)-approved test
5. You have received one or more prior systemic treatment regimens (treatment that affects the entire body)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Keytruda Qlex.

REFERENCES

Keytruda Qlex [Prescribing Information]. Rahway, NJ: Merck & Co., Inc.; July 2026.

Created: 10/25
Effective: 07/29/26 Client Approval: 07/26 DMC Approval: 07/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMETREXED (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMETREXED DISODIUM	ALIMTA, PEMETREXED DISODIUM, PEMRYDI RTU	25905		GPI-10 (2130005310)	
PEMETREXED	PEMFEXY, PEMETREXED	43305		GPI-10 (2130005300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) and meet **ONE** of the following criteria?
   - The requested medication will be used in combination with cisplatin
   - The requested medication will be used as a single agent, maintenance therapy, AND the patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy (e.g., cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic, non-squamous, non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with pembrolizumab and platinum chemotherapy (e.g., cisplatin, carboplatin)
   - The patient does not have EGFR or ALK genomic tumor aberrations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The requested medication will be used as a single agent
   - The patient has received prior chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #5.
   If no, continue to #6.

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PEMETREXED (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The requested medication will be used in combination with Tagrisso (osimertinib) and platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The requested medication will be used in combination with Rybrevant (amivantamab-vmjw) and carboplatin

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient have a diagnosis of malignant pleural mesothelioma and meet **ALL** of the following criteria?
   - The requested medication is being used in combination with cisplatin
   - The patient's disease is unresectable OR the patient is not a candidate for curative surgery

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

7. Is the request for an FDA-approved indication **AND** the requested medication will be used in combination with another chemotherapy agent(s)?
   (NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with pemetrexed. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.**)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEMETREXED (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEMETREXED (Alimta, Pemfexy, Pemrydi RTU)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to nearby tissue or lymph nodes or other parts of the body)
   2. Metastatic, non-squamous, non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread to other parts of the body)
   3. Recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC) (a type of lung cancer that has returned and spread to other parts of the body)
   4. Locally advanced or metastatic non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or other parts of the body)
   5. Malignant pleural mesothelioma (a type of cancer)
   6. The requested medication is being used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

B. If you have locally advanced or metastatic, non-squamous, non-small cell lung cancer, approval also requires ONE of the following:
   1. The requested medication will be used in combination with cisplatin
   2. The requested medication will be used as a single agent, maintenance therapy AND your disease has not progressed (gotten worse) after four cycles of platinum-based first-line chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin)

C. If you have metastatic, non-squamous, non-small cell lung cancer, approval also requires:
   1. The requested medication will be used in combination with pembrolizumab and platinum chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin)
   2. You do NOT have EGFR (epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genomic tumor aberrations (types of gene mutations)

D. If you have recurrent, metastatic non-squamous, non-small cell lung cancer, approval also requires:
   1. The requested medication will be used as a single agent
   2. You have received prior chemotherapy

(Denial text continued on next page)

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PEMETREXED (NSA)

GUIDELINES FOR USE (CONTINUED)

E. If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following criteria:
   a. The requested medication will be used in combination with Tagrisso (osimertinib) and platinum-based chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin)
   b. The requested medication will be used in combination with Rybrevant (amivantamab-vmjw) and carboplatin

F. If you have malignant pleural mesothelioma, approval also requires:
1. The requested medication will be used in combination with cisplatin
2. Your disease is unresectable (cannot be completely removed by surgery) OR you are not a candidate for curative surgery

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Alimta, Pemfexy, and Pemrydi RTU.

REFERENCES
Alimta [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; August 2022.
Pemfexy [Prescribing Information]. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc.; December 2022.
Pemrydi RTU [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; June 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 11/13
Client Approval: 03/24
P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMETREXED DIPOTASSIUM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMETREXED DIPOTASSIUM	AXTLE, PEMETREXED DIPOTASSIUM	49734		GPI-10 (2130005308)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34)?

   If yes, continue to #2.
   If no, continue to #5.

2. Is the patient's cancer metastatic and the patient meets **ALL** of the following criteria?
   - The requested medication will be used in combination with Keytruda (pembrolizumab) and platinum chemotherapy (e.g., cisplatin, carboplatin)
   - The patient's cancer does NOT have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient's cancer locally advanced or metastatic and the patient meets **ONE** of the following criteria?
   - The requested medication will be used in combination with cisplatin
   - The requested medication will be used as a single agent AND the patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy (e.g., cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient's cancer recurrent and metastatic **AND** the patient meets the following criterion?
   - The patient has received prior chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEMETREXED DIPOTASSIUM

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of malignant pleural mesothelioma (ICD-10 C45.0) and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with cisplatin
   - The patient's disease is unresectable OR the patient is not a candidate for curative surgery

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Is the request for an FDA-approved indication **AND** the requested medication will be used in combination with another chemotherapy agent(s)?
   (NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with pemetrexed. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.**)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEMETREXED DIPOTASSIUM (Axtle)** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Non-squamous non-small cell lung cancer (NSCLC) (a type of lung cancer)
      2. Malignant pleural mesothelioma (a type of cancer)
      3. The requested medication will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

   (Denial text continued on next page)

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PEMETREXED DIPOTASSIUM

GUIDELINES FOR USE (CONTINUED)

B. If you have non-squamous, non-small cell lung cancer, approval also requires ONE of the following:

1. Your cancer is metastatic (has spread to other parts of the body), the requested medication will be used in combination with Keytruda (pembrolizumab) and platinum chemotherapy (such as cisplatin, carboplatin), AND you do NOT have epidermal growth factor receptor (EGFR: a type of protein) or anaplastic lymphoma kinase (ALK: a type of protein) genomic tumor aberrations (types of gene mutations)
2. Your cancer is locally advanced (has spread to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body), AND the requested medication will be used in combination with cisplatin
3. Your cancer is locally advanced (has spread to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body), the requested medication will be used as a single agent, AND your disease has not progressed (gotten worse) after four cycles of platinum-based first-line chemotherapy (a type of therapy to treat cancer such as cisplatin, carboplatin)
4. Your cancer is recurrent (has returned) and metastatic (has spread to other parts of the body), AND you have received prior chemotherapy (medication used to treat cancer)

C. If you have malignant pleural mesothelioma, approval also requires:

1. The requested medication will be used in combination with cisplatin
2. Your disease is unresectable (cannot be completely removed by surgery) OR you are not a candidate for curative (to cure) surgery

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for pemetrexed dipotassium.

REFERENCES

Axtle [Prescribing Information]. New Jersey, USA: Avyxa Pharma, LLC; October 2025.
Pemetrexed dipotassium [Prescribing Information]. Parsippany, NJ: Avyxa Pharma, LLC; June 2024.

Created: 12/24
Effective: 11/01/25 Client Approval: 10/25 P&T Approval: 01/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMETREXED DITROMETHAMINE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMETREXED DITROMETHAMINE	PEMETREXED DITROMETHAMINE			GPI-10 (2130005320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) and meet **ONE** of the following criteria?
   - The requested medication will be used in combination with cisplatin
   - The requested medication will be used as a single agent, maintenance therapy, AND the patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy (e.g., cisplatin, carboplatin)

   If yes, **approve for 12 months by GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The requested medication will be used as a single agent
   - The patient has received prior chemotherapy

   If yes, **approve for 12 months by GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older

   If yes, continue to #4.
   If no, continue to #5.

4. Does the patient meet **ONE** of the following criteria?
   - The requested medication will be used in combination with Tagrisso (osimertinib) and platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The requested medication will be used in combination with Rybrevant (amivantamab-vmjw) and carboplatin

   If yes, **approve for 12 months by GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PEMETREXED DITROMETHAMINE (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of malignant pleural mesothelioma and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with cisplatin
   - The patient's disease is unresectable OR the patient is not a candidate for curative surgery

   If yes, **approve for 12 months by GPI-10.**
   If no, continue to #6.

6. Is the request for an FDA-approved indication **AND** the requested medication will be used in combination with another chemotherapy agent(s)?
   (NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with pemetrexed. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.**)

   If yes, **approve for 12 months by GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEMETREXED DITROMETHAMINE** requires the following rule(s) be met for approval:
   A. The request is for ONE of the following:
      1. Locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to nearby tissue/lymph nodes or other part of the body)
      2. Recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
      3. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or other parts of the body)
      4. Malignant pleural mesothelioma (a type of cancer)
      5. The requested medication is being used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

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PEMETREXED DITROMETHAMINE (NSA)

GUIDELINES FOR USE (CONTINUED)

B. If you have locally advanced or metastatic, non-squamous, non-small cell lung cancer, approval also requires ONE of the following:
1. The requested medication will be used in combination with cisplatin
2. The requested medication will be used as a single agent, maintenance therapy AND your disease has not progressed (gotten worse) after four cycles of platinum-based first-line chemotherapy (e.g., cisplatin, carboplatin)

C. If you have recurrent, metastatic non-squamous, non-small cell lung cancer, approval also requires:
1. The requested medication will be used as a single agent
2. You have received prior chemotherapy

D. If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following criteria:
   a. The requested medication will be used in combination with Tagrisso (osimertinib) and platinum-based chemotherapy (such as cisplatin, carboplatin)
   b. The requested medication will be used in combination with Rybrevant (amivantamab-vmjw) and carboplatin

E. If you have malignant pleural mesothelioma, approval also requires:
1. The requested medication will be used in combination with cisplatin
2. Your disease is unresectable (cannot be completely removed by surgery) OR you are not a candidate for curative surgery

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for pemetrexed ditromethamine.

REFERENCES
Pemetrexed ditromethamine [Prescribing Information]. Lake Forest, IL: Hospira, Inc.; June 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 08/22
Client Approval: 03/24
P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMIGATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMIGATINIB	PEMAZYRE	46462		GPI-10 (2153226000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma (ICD-10 C22.1, C24.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been previously treated for unresectable locally advanced or metastatic cholangiocarcinoma
   - The patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement, as detected by an FDA-approved test
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10 for #14 per 21 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) (ICD-10 C96.9, C96.Z; Groups C94.8, C95.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a fibroblast growth factor receptor 1 (FGFR1) rearrangement
   - The patient will complete a comprehensive ophthalmological examination, including optical coherence tomography (OCT), prior to initiation of therapy and at the recommended scheduled intervals

   If yes, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEMIGATINIB (Pemazyre)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread to nearby tissue and lymph nodes and cannot be removed by surgery, or it has spread to other parts of the body)
      2. Relapsed or refractory myeloid/lymphoid neoplasms (a type of blood cancer that has returned or did not respond to treatment)

   (Denial text continued on next page)

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PEMIGATINIB

GUIDELINES FOR USE (CONTINUED)

B. If you have unresectable locally advanced or metastatic cholangiocarcinoma, approval also requires:
1. You are 18 years of age or older
2. You have previously been treated for unresectable locally advanced or metastatic cholangiocarcinoma
3. You have a fibroblast growth factor receptor 2 (FGFR2: a type of protein) fusion or other rearrangement as detected by a Food and Drug Administration (FDA)-approved test
4. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

C. If you have relapsed or refractory myeloid/lymphoid neoplasms, approval also requires:
1. You are 18 years of age or older
2. You have a fibroblast growth factor receptor 1 (FGFR1: a type of protein) rearrangement
3. You will complete a comprehensive ophthalmological examination (eye exam), including optical coherence tomography (OCT: a type of eye imaging test), before starting the medication and at the recommended scheduled times

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Pemazyre.

REFERENCES
Pemazyre [Prescribing Information]. Wilmington, DE: Incyte Corporation; June 2023.

Created: 07/20
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 10/22

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEMIVIBART (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMIVIBART	PEMGARDA (EUA)	49474		GPI-10 (1950206300)	

GUIDELINES FOR USE

1. Is the request for pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient weighs at least 40 kg (88 lbs)
   - The patient is NOT currently infected with SARS-CoV-2 virus
   - The patient has NOT had a recent exposure to an individual infected with the SARS-CoV-2 virus
   - The patient is moderately-to-severely immunocompromised due to a medical condition (e.g., HIV, primary immunodeficiency disease, acute leukemia) OR immunosuppressive medication or treatment (e.g., sirolimus, mycophenolate, chemotherapy)
   - The patient is unlikely to have an adequate immune response to the COVID-19 vaccination

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #36 mL per 3 months.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEMIVIBART (Pemgarda)** requires the following rule(s) be met for approval:
   A. The request is for pre-exposure prophylaxis (to prevent infection) of coronavirus disease 2019 (COVID-19: a type of viral infection)
   B. You are 12 years of age or older
   C. You weigh at least 40 kilograms (88 pounds)
   D. You are NOT currently infected with the SARS-CoV-2 virus (a type of virus that causes COVID-19 illness)
   E. You have NOT been recently exposed to (come in contact with) an individual infected with the SARS-CoV-2 virus
   F. You are moderately-to-severely immunocompromised (low immune system) due to a medical condition (such as HIV [human immunodeficiency virus: an immune system disease caused by a virus], primary immunodeficiency disease [genetic disease where the immune system is weak], acute leukemia [a type of blood cancer]) OR immunosuppressive medication or treatment (such as sirolimus, mycophenolate, chemotherapy [a type of cancer treatment])

   (Denial text continued on next page)

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PEMIVIBART (NSA)

GUIDELINES FOR USE (CONTINUED)

G. You are unlikely to have an adequate immune response to the COVID-19 vaccination (vaccine may not work effectively for you)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pemgarda.

REFERENCES

Pemgarda [Prescribing Information]. Waltham, MA: Invivyd, Inc.; March 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/12/24
Created: 04/24
Client Approval: 08/24
P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PENICILLAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PENICILLAMINE	CUPRIMINE, PENICILLAMINE		7091	GPI-14 (99200030000110)	
PENICILLAMINE	DEPEN, PENICILLAMINE		7100	GPI-14 (99200030000305)	
PENICILLAMINE	D-PENAMINE		7101	GPI-14 (99200030000302)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for D-Penamine and the patient has an active prior authorization approval for Depen? ***[Note: D-Penamine is temporarily available to address a critical drug shortage of Depen. Patients previously approved for Depen will be allowed access without additional criteria during this shortage.]***

If yes, **approve D-Penamine for 12 months by GPID or GPI-14 for the requested indication as follows:**
- **Wilson's Disease: #16 per day.**
- **Active Rheumatoid Arthritis: #12 per day.**
- **Cystinuria: #32 per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The requested medication will be used with a dietary plan to maintain a copper intake of less than 0.9 mg/day

   If yes, continue to #3.
   If no, continue to #7.

3. Does the patient have genetic testing confirming an ATP7B mutation?

   If yes, continue to #5.
   If no, continue to #4.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient has a 24-hour urinary copper excretion (greater than 40 micrograms/24 hours)
   - The patient has a liver biopsy with copper dry weight greater than 75 micrograms/gram
   - The patient has a serum ceruloplasmin level of less than 20 mg/dL

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the request for Depen or D-Penamine?

   If yes, **approve for lifetime by GPID or GPI-14 for the requested medication as follows:**
   - **Depen: #8 per day.**
   - **D-Penamine: #16 per day.**

   If no, continue to #6.

6. Is the request for Cuprimine **AND** the patient had a trial of or contraindication to the preferred agent: penicillamine (Depen, D-Penamine)?

   If yes, **approve Cuprimine for lifetime by GPID or GPI-14 with a quantity limit of #8 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of cystinuria (ICD-10 E72.01) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a nephrologist or urologist
   - The patient has failed to respond to an adequate trial of or has a contraindication to conservative therapy which includes ALL of the following: increased fluid intake, reductions in sodium and protein intake, and urinary alkalinization

   If yes, continue to #8.
   If no, continue to #11.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

8. Does the patient have nephrolithiasis (ICD-10 N20.0) and meet **ONE** of the following criteria?
   - The patient's stone analysis shows a presence of cystine
   - The patient's urinalysis shows pathognomonic hexagonal cystine crystals
   - The patient has a family history of cystinuria AND a positive cyanide-nitroprusside screening

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Is the request for Depen (penicillamine tablets) or D-Penamine **AND** the patient had a trial of or contraindication to the preferred agent: penicillamine capsules (Cuprimine)?

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following as follows:**
   - **Depen: #16 per day.**
   - **D-Penamine: #32 per day.**

   If no, continue to #10.

10. Is the request for Cuprimine (penicillamine capsules)?

    If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity of #16 per day.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

11. Does the patient have a diagnosis of active rheumatoid arthritis (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
    - Therapy is prescribed by or in consultation with a rheumatologist
    - The patient does not have a history or other evidence of renal insufficiency
    - The patient has failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, sulfasalazine

    If yes, continue to #12.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

12. Is the request for Depen or D-Penamine?

    If yes, **approve for 12 months by GPID or GPI-14 for the requested medication as follows:**
    - **Depen: #6 per day.**
    - **D-Penamine: #12 per day.**

    If no, continue to #13.

13. Is the request for Cuprimine **AND** has the patient had a trial of or contraindication to the preferred agent: penicillamine (Depen, D-Penamine)?

    If yes, **approve Cuprimine for 12 months by GPID or GPI-14 with a quantity of #6 per day.** If no, do not approve.

    INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for approval:
    A. You have ONE of the following:
        1. Wilson's disease (a type of genetic disorder)
        2. Cystinuria (a type of genetic disorder)
        3. Severe, active rheumatoid arthritis (a type of joint condition)

    (Initial denial text continued on next page)

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

B. If you have Wilson's disease, approval also requires:
1. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
2. The requested medication will be used with a dietary plan to maintain a copper intake of less than 0.9 mg/day
3. You meet ONE of the following:
   a. You have genetic testing confirming an ATP7B mutation (an abnormal change in a type of gene)
   b. You meet ONE of the following:
      i. You have a 24-hour urinary copper excretion (a type of lab test) (greater than 40 micrograms/24 hours)
      ii. You have a liver biopsy (removal of cells or tissue from the liver for examination) with copper dry weight greater than 75 micrograms/gram
      iii. You have a serum ceruloplasmin (a type of lab test) level less than 20mg/dL
4. If you are requesting Cuprimine, you have tried or have a contraindication to (harmful for you to use) the preferred medication: penicillamine (Depen, D-Penamine)

C. If you have cystinuria, approval also requires:
1. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor) or urologist (a type of doctor who treats conditions affecting the organs in the body that make and remove urine)
2. You have failed to respond to an adequate trial of or have a contraindication to (harmful for you to use) conservative therapy which includes ALL of the following:
   a. Increased fluid intake
   b. Reductions in sodium and protein intake
   c. Urinary alkalinization (a process that makes urine basic)
3. You have nephrolithiasis (kidney stones) and meet ONE of the following:
   a. Your kidney stone analysis shows that there is a presence of cystine (an amino acid)
   b. Your urine analysis shows that there are hexagonal cystine crystals in your urine that are pathognomonic (signs relating to the disease)
   c. You have a family history of cystinuria (a type of genetic disorder) AND tested positive for the cyanide-nitroprusside screen (a test to determine the amount of cysteine in your body)
4. If you are requesting Depen (penicillamine tablets) or D-Penamine, you have tried or have a contraindication to (harmful for you to use) the preferred medication: penicillamine capsules (Cuprimine)

(Initial denial text continued on next page)

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

D. If you have active rheumatoid arthritis, approval requires:
1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
2. You do not have a history or other evidence of renal insufficiency (kidney problems)
3. You have failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
4. If you are requesting Cuprimine, you have tried or have a contraindication to (harmful for you to use) the preferred medication: penicillamine (Depen, D-Penamine)

E. **If you have an active prior authorization approval for Depen, D-Penamine** will be approved without meeting additional criteria during the period of Depen shortage.

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PENICILLAMINE

RENEWAL CRITERIA

NOTE: For the diagnosis of Wilson's disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of cystinuria (ICD-10 E72.01) **AND** meet the following criterion?
   - The patient has decreased urinary cysteine concentration

   If yes, **approve for lifetime by GPID or GPI-14 for all of the following as follows:**
   - **Depen: #16 per day.**
   - **D-Penamine: #32 per day.**
   - **Cuprimine: #16 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of active rheumatoid arthritis (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient does not have a history of or other evidence of renal insufficiency
   - The patient has experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

   If yes, **approve for lifetime by GPID or GPI-14 for all of the following as follows:**
   - **Depen: #6 per day.**
   - **D-Penamine: #12 per day.**
   - **Cuprimine: #6 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Cystinuria (a type of genetic disorder)
      2. Active rheumatoid arthritis (a type of joint condition)

   B. If you have cystinuria, renewal also requires:
      1. You have decreased urinary cysteine concentration (a type of lab test for a type of protein building block)

   C. If you have active rheumatoid arthritis, renewal also requires:
      1. You do not have a history of or other evidence of renal insufficiency (kidney problems)
      2. You have experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

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PENICILLAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cuprimine/Depen.

REFERENCES

Cuprimine [Prescribing Information]. Bridgewater, NJ: Bausch Health Companies Inc.; October 2025.

Depen [Prescribing Information]. Morgantown, WV: Viatris Specialty LLC; September 2025.

FDA Website: Penicillamine (Depen) Titratable Tablets Drug Shortage. Available at: https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillamine%20(Depen)%20Titratable%20Tablets&st=c. Accessed on January 21, 2019

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PENTOSAN POLYSULFATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PENTOSAN POLYSULFATE SODIUM	ELMIRON	08734		GPI-10 (5650006010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of interstitial cystitis/bladder pain syndrome (ICD-10 Group N30.1) and meet **ALL** of the following criteria?
   - The patient has experienced ongoing symptoms for at least six weeks
   - Therapy is prescribed by or in consultation with a urologist
   - The patient had a retinal exam or a detailed ophthalmic history performed/collected prior to starting therapy
   - The patient had a trial of or contraindication to the following preferred agent: ONE guideline recommended alternative generic agent (e.g., amitriptyline, hydroxyzine, cimetidine)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for approval:
   A. You have interstitial cystitis (painful bladder condition)/bladder pain syndrome
   B. You have experienced ongoing symptoms for at least six weeks
   C. Therapy is prescribed by or in consultation with a urologist (a type of doctor who treats conditions affecting the organs in the body that make and remove urine)
   D. You had a retinal (eye) exam or a detailed ophthalmic (eye) history performed/collected prior to starting therapy
   E. You have tried or have a contraindication to (harmful for you to use) the following preferred agent: ONE guideline recommended alternative generic medication (such as amitriptyline, hydroxyzine, cimetidine)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PENTOSAN POLYSULFATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of interstitial cystitis/bladder pain syndrome (ICD-10 Group N30.1) and meet **ALL** of the following criteria?
   - The patient has experienced clinical improvement from baseline secondary to treatment
   - The patient has NOT experienced any visual changes/adverse effects related to Elmiron

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for renewal:
   A. You have interstitial cystitis (painful bladder condition)/bladder pain syndrome
   B. You have experienced clinical improvement (observable improvement) from baseline (before treatment) due to treatment
   C. You have NOT experienced any visual changes (change in how you see)/adverse effects (side effects) related to Elmiron

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elmiron.

REFERENCES

Elmiron [Prescribing Information]. Titusville, New Jersey: Janssen Pharmaceuticals, Inc.; September 2024

Created: 02/20
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PERTUZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PERTUZUMAB	PERJETA	39102		GPI-10 (2117005400)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient's breast cancer is HER2-positive

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's cancer metastatic and the patient meets **ALL** of the following criteria?
   - The patient has not received prior therapy with an anti-HER2 agent or chemotherapy for metastatic disease
   - Perjeta will be used in combination with trastuzumab (Herceptin or an FDA approved biosimilar) and docetaxel

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient's cancer locally advanced, inflammatory, or early stage (either greater than 2 cm in diameter or node positive) and the patient meets **ALL** of the following criteria?
   - Perjeta will be used in the neoadjuvant setting
   - Perjeta will be used in combination with trastuzumab (Herceptin or an FDA approved biosimilar) and chemotherapy (e.g., paclitaxel, carboplatin, cyclophosphamide) as part of a complete treatment regimen for early breast cancer

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

4. Is the patient's disease early breast cancer (EBC) and the patient meets **ALL** of the following criteria?
   - The patient's breast cancer is at high risk of recurrence
   - Perjeta will be used in the adjuvant setting
   - Perjeta will be used in combination with trastuzumab (Herceptin or an FDA approved biosimilar) and chemotherapy (e.g., paclitaxel, carboplatin, cyclophosphamide)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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PERTUZUMAB

GUIDELINES FOR USE (CONTINUED)

5. Is the patient's cancer unresectable or metastatic and the patient meets **ALL** of the following criteria?
   - The patient's cancer is IHC 3+ or ISH positive, as determined by an FDA-approved test
   - Perjeta will be used in combination with fam-trastuzumab deruxtecan-nxki (Enhertu)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PERTUZUMAB (Perjeta)** requires the following rule(s) be met for approval:
   A. You have breast cancer
   B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   C. If you have metastatic breast cancer (cancer that has spread to other parts of the body), approval also requires:
      1. You have not received prior therapy with an anti-HER2 agent or chemotherapy for metastatic disease (treatment for cancer that has spread to other parts of the body)
      2. Perjeta will be used in combination with trastuzumab and docetaxel
   D. If you have locally advanced (cancer that has spread to nearby tissue or lymph nodes), inflammatory, or early stage breast cancer (defined as either tumor is greater than 2 cm in diameter or node positive), approval also requires:
      1. Perjeta will be used in the neoadjuvant setting (given before main treatment)
      2. Perjeta will be used in combination with trastuzumab and chemotherapy (such as paclitaxel, carboplatin, or cyclophosphamide) as part of a complete drug regimen for early breast cancer
   E. If you have early breast cancer, approval also requires:
      1. Your breast cancer is at high risk of recurrence (returning)
      2. Perjeta will be used in the adjuvant setting (given as add-on treatment)
      3. Perjeta will be used in combination with trastuzumab and chemotherapy (such as paclitaxel, carboplatin, or cyclophosphamide)
   F. If you have unresectable or metastatic breast cancer (cancer that cannot be removed by surgery or has spread to other parts of the body), approval also requires:
      1. Your breast cancer is IHC 3+ or ISH positive, as determined by a Food and Drug Administration (FDA)-approved test
      2. You will use Perjeta in combination with fam-trastuzumab deruxtecan-nxki (Enhertu)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PERTUZUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Perjeta.

REFERENCES

Perjeta [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; October 2020.
Enhertu [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; December 2025.

Created: 08/12
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 01/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PERTUZUMAB-TRASTUZUMAB-HY-ZZXF	PHESGO	46674		GPI-10 (2199000355)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced, inflammatory, or early breast cancer (either greater than 2 cm in diameter or node positive) and meet **ALL** of the following criteria?
   - The patient's breast cancer is HER2-positive
   - The requested medication will be used in combination with chemotherapy as part of a complete treatment regimen for early breast cancer in the neoadjuvant setting

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 21 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of early breast cancer at high risk of recurrence and meet **ALL** of the following criteria?
   - The patient's breast cancer is HER2-positive
   - The requested medication will be used in combination with chemotherapy in the adjuvant setting

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 21 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient's breast cancer is HER2-positive
   - The patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease
   - The requested medication is being used in combination with docetaxel

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 21 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (Phesgo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Locally advanced, inflammatory, or early breast cancer (tumor is greater than 2 cm in diameter or node positive)
   2. Early breast cancer at high risk of recurrence (returning)
   3. Metastatic breast cancer (breast cancer has spread to other parts of the body)

B. If you have locally advanced, inflammatory or early breast cancer (tumor is greater than 2 cm in diameter or node positive), approval also requires:
   1. Your breast cancer is HER2-positive
   2. The requested medication will be used in combination with chemotherapy as part of a complete treatment regimen for early breast cancer in the neoadjuvant setting (given before surgery)

C. If you have early breast cancer at high risk of recurrence, approval also requires:
   1. Your breast cancer is HER2-positive
   2. The requested medication will be used in combination with chemotherapy in the adjuvant setting (given as add-on treatment)

D. If you have metastatic breast cancer, approval also requires:
   1. Your breast cancer is HER2-positive
   2. You have not previously received anti-HER2 therapy or chemotherapy for metastatic disease
   3. The requested medication is being used in combination with docetaxel

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Phesgo.

REFERENCES

Phesgo [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 10/20
Client Approval: 11/20
P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEXIDARTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEXIDARTINIB HYDROCHLORIDE	TURALIO	45912		GPI-10 (2153304501)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) (ICD-10 D48.1; Group M12.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - TGCT is associated with severe morbidity or functional limitations
   - TGCT is NOT amenable to improvement with surgery

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEXIDARTINIB (Turalio)** requires the following rules be met for approval:
   A. You have symptomatic tenosynovial giant cell tumor (TGCT: a type of non-cancerous growth in the soft tissue around a joint)
   B. You are 18 years of age or older
   C. TGCT is associated with severe morbidity (disease) or functional limitations
   D. TGCT is NOT responsive to improvement with surgery

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Turalio.

REFERENCES

Turalio [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; January 2025.

Created: 08/19
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PHENOXYBENZAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PHENOXYBENZAMINE HCL	DIBENZYLINE, PHENOXYBENZA -MINE HCL	02098		GPI-10 (3630001010)	FDB: ROUTE = ORAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pheochromocytoma (ICD-10 Groups D35.0, C74.1) and meet **ALL** of the following criteria?
   - The requested medication will be used prior to pheochromocytoma resection/removal
   - Therapy is prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist-oncologist
   - The patient had a trial of or contraindication to an alpha-1 selective adrenergic receptor blocker (e.g., doxazosin, terazosin, prazosin)

   If yes, **approve for 30 days by HICL or GPI-10 with a quantity limit of #168 per 14 days for 1 fill.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PHENOXYBENZAMINE (Dibenzyline)** requires the following rules be met for approval:
   A. You have pheochromocytoma (a type of rare tumor)
   B. The requested medication will be used before surgery to remove the tumor
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist-oncologist (a type of cancer doctor)
   D. You have tried or have a contraindication to (harmful for you to use) an alpha-1 selective adrenergic receptor blocker (such as doxazosin, terazosin, prazosin)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PHENOXYBENZAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dibenzyline.

REFERENCES

Dibenzyline [Prescribing Information]. Bannockburn, IL: Advanz Pharma; December 2024.

Created: 08/18
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PHENTERMINE - TOPIRAMATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PHENTERMINE/ TOPIRAMATE	QSYMIA, PHENTERMINE-TOPIRAMATE ER	39347		GPI-10 (6120990230)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Are weight loss products (anti-obesity medications) a covered benefit?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for weight loss OR weight management (ICD-10 Group E66) **AND** the patient meets the following criterion?
   - There is physician attestation of active enrollment in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)

   If yes, **approve for 14 weeks by HICL or GPI-10 with a quantity limit of #1 per day**
   If no, continue to #4.

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PHENTERMINE - TOPIRAMATE

INITIAL CRITERIA (CONTINUED)

4. Is the patient 12 to 17 years of age **AND** meets the following criterion?
   - The patient's initial body mass index (BMI) is in the 95th percentile or greater for age and sex (see table below)

95th Percentile BMI Value for Age and Sex

Age (in years)	Male	Female
	95th Percentile BMI Value	95th Percentile BMI Value
12	24.2	25.3
12.5	24.7	25.8
13	25.2	26.3
13.5	25.6	26.8
14	26.0	27.3
14.5	26.5	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.6	28.9
16.5	27.9	29.3
17	28.3	29.6
17.5	28.6	30.0

If yes, **approve for 14 weeks by HICL or GPI-10 with a quantity limit of #1 per day .**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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PHENTERMINE - TOPIRAMATE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PHENTERMINE - TOPIRAMATE (Qsymia)** requires the following rule(s) be met for approval:

A. The request is for weight loss or weight management
B. You are 12 years of age or older
C. You are actively enrolled in an exercise and caloric reduction program which may include use of an optional weight loss/behavioral modification program
D. If you are 18 years of age or older, approval also requires:
    1. You meet ONE of the following before starting weight loss therapy:
        a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
        b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
        c. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
        d. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
E. If you are 12 to 17 years of age, approval also requires:
    1. Your initial body mass index (BMI: a tool for evaluating body fat) is in the 95th percentile or greater for age and sex

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PHENTERMINE - TOPIRAMATE

RENEWAL CRITERIA

1. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 12 to 17 years of age **AND** meets the following criterion?
   - The patient has achieved or maintained at least a 3% to 5% weight loss of baseline BMI after 3 months of treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Is the patient 18 years of age or older and meets **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PHENTERMINE - TOPIRAMATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PHENTERMINE - TOPIRAMATE (Qsymia)** requires the following rule(s) be met for renewal:

A. The request is for weight loss or weight management

B. If you are 12 to 17 years of age, approval also requires:

1. You have achieved or maintained at least a 3% to 5% weight loss of baseline body mass index (BMI: a tool for evaluating body fat) after 3 months of treatment

C. If you are 18 years of age or older, approval also requires:

1. You meet ONE of the following before starting weight loss therapy:
   a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
   b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
   c. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
   d. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], or hyperlipidemia [high cholesterol])
2. You have achieved or maintained at least a 5% weight loss of baseline body weight after 3 months of treatment

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qsymia.

REFERENCES

Qsymia [Prescribing Information]. Campbell, CA: Vivus LLC; March 2026.

Created: 05/24
Effective: 04/10/26 Client Approval: 04/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIMAVANSERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIMAVANSERIN TARTRATE	NUPLAZID	43373		GPI-10 (5940002820)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of psychosis (ICD-10 F02.82, F02.A2, F02.B2, F02.C2) associated with Parkinson's disease (ICD-10 Group G20) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, geriatrician, or behavioral health specialist (e.g., psychiatrist)

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **34mg: #1 per day.**
   - **17mg: #2 per day.**
   - **10mg: #1 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIMAVANSERIN (Nuplazid)** requires you to meet the following rule(s) for approval:
   A. You have psychosis (a type of mental health disorder) associated with Parkinson's disease (PD: a type of movement disorder)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), geriatrician (a doctor who specializes in the health care of older adults), or behavioral health specialist (such as a psychiatrist [a type of mental health doctor])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIMAVANSERIN

RENEWAL CRITERIA

1. During the past 12 months of therapy has the patient experienced an improvement in psychosis symptoms from baseline **AND** does the patient demonstrate a continued need for treatment?

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **34mg: #1 per day.**
   - **17mg: #2 per day.**
   - **10mg: #1 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIMAVANSERIN (Nuplazid)** requires the following rule(s) be met for renewal:
   A. You have experienced improvement in symptoms of psychosis (a type of mental health disorder) from baseline during the past 12 months of therapy, AND you show a continued need for treatment

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuplazid.

REFERENCES
Nuplazid [Prescribing Information]. San Diego, CA: Acadia Pharmaceuticals Inc.; January 2025.

Created: 04/16
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 05/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIRFENIDONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIRFENIDONE	ESBRIET, PIRFENIDONE	40237		GPI-10 (4555006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a pulmonologist
   - The patient does NOT have other known causes of interstitial lung disease (ILD) (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus [HIV] infection, viral hepatitis, cancer)
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient does NOT currently smoke cigarettes
   - Esbriet will NOT be used concurrently with Ofev

   If yes, **enter TWO authorizations for a total of 12 months as follows:**
   <u>FIRST APPROVAL:</u> Approve all strengths for 1 month by GPID or GPI-14 with the following quantity limits:
   - **267mg: #9 per day.**
   - **534mg: #3 per day.**
   - **801mg: #3 per day.**

   <u>SECOND APPROVAL:</u> Approve for 11 months by HICL or GPI-10 with a quantity limit of #3 per day (enter a start date of 2 days BEFORE the end of the first approval).

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PIRFENIDONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for approval:

A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
B. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
C. You do NOT have other known causes of interstitial lung disease (ILD: a type of lung condition) (such as connective tissue disease [a type of autoimmune disorder], drug toxicity, asbestos [a type of mineral that can be toxic] or beryllium [a type of metal that can be toxic] exposure, hypersensitivity pneumonitis [a type of lung condition], systemic sclerosis [a type of autoimmune disorder], rheumatoid arthritis [a type of joint condition], radiation, sarcoidosis [a type of inflammatory disorder], bronchiolitis obliterans organizing pneumonia [a type of lung condition], human immunodeficiency virus [HIV: an immune system disease caused by a virus] infection, viral hepatitis [type of liver inflammation], cancer)
D. You have a usual interstitial pneumonia pattern (UIP: a specific type of lung scarring) as shown by high-resolution computed tomography (HRCT: type of imaging test) alone or by a combination of surgical lung biopsy (removal of cells or tissue from the body for examination) and HRCT
E. You do NOT currently smoke cigarettes
F. You will NOT use Esbriet concurrently (at the same time) with Ofev

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIRFENIDONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) (ICD-10 J84.112) and meet **ALL** of the following criteria?
   - The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline
   - Esbriet will NOT be used concurrently with Ofev

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for renewal:
   A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
   B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
   C. You will NOT use Esbriet concurrently (at the same time) with Ofev

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Esbriet.

REFERENCES

Esbriet [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; February 2023.

Created: 02/15
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIRTOBRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIRTOBRUTINIB	JAYPIRCA	48657		GPI-10 (2153216500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL) (ICD-10 Group C83.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least TWO lines of systemic therapy including a Bruton tyrosine kinase (BTK) inhibitor (e.g., Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **50 mg: #3 per day.**
   - **100 mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received a covalent Bruton's tyrosine kinase (BTK) inhibitor (e.g., Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **50 mg: #3 per day.**
   - **100 mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PIRTOBRUTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PIRTOBRUTINIB (Jaypirca)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Relapsed or refractory mantle cell lymphoma (MCL) (a type of blood cancer that has returned or did not respond to treatment)
   2. Relapsed or refractory chronic lymphocytic leukemia (CLL) (a type of blood cancer that has returned or did not respond to treatment)
   3. Relapsed or refractory small lymphocytic lymphoma (SLL) (a type of blood cancer that has returned or did not respond to treatment)

B. If you have relapsed or refractory mantle cell lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have previously received at least TWO lines of systemic therapy (treatment that targets the entire body), including a BTK inhibitor (Bruton tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

C. If you have relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have previously received a covalent BTK inhibitor (Bruton's tyrosine kinase inhibitor such as Imbruvica [ibrutinib], Calquence [acalabrutinib], Brukinsa [zanubrutinib])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jaypirca.

REFERENCES

Jaypirca [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; December 2025.

Created: 05/23
Effective: 01/12/26 Client Approval: 12/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PITOLISANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PITOLISANT HCL	WAKIX	45575		GPI-10 (6145007010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419) and narcolepsy is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   - The patient has normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient meet **ALL** of the following criteria?
   - The patient has excessive daytime sleepiness (EDS) persisting for at least 3 months and an Epworth Sleepiness Scale (ESS) score of more than 10
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Wakix will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 6 to 17 years of age **AND** meets the following criterion?
   - The patient had a trial of or contraindication to ONE preferred generic typical stimulant (e.g., amphetamine sulfate [Evekeo], methylphenidate [Ritalin])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

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PITOLISANT

INITIAL CRITERIA (CONTINUED)

4. Is the patient 18 years of age or older **AND** meets the following criterion?
   - The patient had a trial of or contraindication to one preferred generic typical stimulant (e.g., amphetamine sulfate [Evekeo], methylphenidate [Ritalin]) AND solriamfetol (Sunosi), armodafinil (Nuvigil), or modafinil (Provigil)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of cataplexy with narcolepsy (ICD-10 G47.411) and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs)
   - The patient has a SOREMP within 15 minutes of sleep onset
   - The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has an Epworth Sleepiness Scale (ESS) score greater than 10
   - Wakix will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
   - The patient has tried TWO of the following preferred agents: venlafaxine, fluoxetine, a TCA (e.g., clomipramine, imipramine)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PITOLISANT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
   2. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. If you have excessive daytime sleepiness with narcolepsy, approval also requires:
   1. You have narcolepsy (a type of sleep condition) that is confirmed by ONE of the following:
      a. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs: time it takes to enter dream sleep)
      b. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP: time it takes to enter dream sleep) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
      c. You have normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have normal levels of a chemical that helps with staying awake)
   2. You have EDS lasting for at least 3 months and an Epworth Sleepiness Scale (ESS: tool to measure your sleepiness) score of more than 10
   3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   4. You will NOT use Wakix concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)

(Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You are 6 to 17 years old AND have tried or have a contraindication to (harmful for you to use) ONE preferred generic typical stimulant (such as amphetamine sulfate [Evekeo], methylphenidate [Ritalin])
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) one preferred generic typical stimulant (such as amphetamine sulfate [Evekeo], methylphenidate [Ritalin]) AND solriamfetol (Sunosi), armodafinil (Nuvigil), or modafinil (Provigil)

C. If you have cataplexy with narcolepsy, approval also requires:

1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You have an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
4. Your narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
   a. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs: time it takes to enter dream sleep)
   b. You have a sleep-onset rapid eye movement period (SOREMP: time it takes to enter dream sleep) within 15 minutes of sleep onset
   c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
5. You will NOT use Wakix concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
6. You have tried TWO of the following preferred medications: venlafaxine, fluoxetine, a TCA (tricyclic antidepressant such as clomipramine, imipramine)

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PITOLISANT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419) or cataplexy with narcolepsy (ICD-10 G47.411) **AND** meet the following criterion?
   - Wakix will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated at least a 25% improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline
   - The patient has shown improvement in cataplexy symptoms compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)
      2. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
   B. You will NOT use Wakix concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant]
   C. You meet ONE of the following:
      1. You have demonstrated at least a 25% improvement in Epworth Sleepiness Scale (ESS: tool to measure your sleepiness) scores compared to baseline
      2. You have shown improvement in cataplexy (sudden and uncontrollable muscle weakness) symptoms compared to baseline
      3. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep) from baseline

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PITOLISANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wakix.

REFERENCES

Wakix [Prescribing Information]. Plymouth Meeting, PA: Harmony Biosciences, LLC; February 2026.

Created: 10/19
Effective: 08/28/26 Client Approval: 08/26 DMC Approval: 08/18/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIVMECILLINAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIVMECILLINAM HCL	PIVYA	07565		GPI-10 (0150007040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of an uncomplicated urinary tract infection (uUTI) (ICD-10 N39.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a female

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - Therapy is prescribed by or in consultation with an Infectious Disease (ID) specialist
   - Therapy is a continuation of care from an inpatient setting

   If yes, **approve for 1 month by HICL or GPI-10 with a quantity limit of #21 for #1 fill.**
   If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?
   - The culture shows that the patient's infection is caused by a multidrug-resistant bacteria
   - The organism from the culture is sensitive to Pivya
   - The organism from the culture is resistant OR the patient has a contraindication to other beta- lactams (e.g., cefdinir, cefaclor), fluoroquinolones (e.g., ciprofloxacin, levofloxacin), cephalosporins, penicillins, nitrofurantoin, and TMP-SMX

   If yes, **approve for 1 month by HICL or GPI-10 with a quantity limit of #21 for #1 fill.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PIVMECILLINAM

GUIDELINE FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PIVMECILLINAM (Pivya)** requires the following rule(s) be met for approval:

A. You have uncomplicated urinary tract infection (uUTI: a type of bacterial infection)
B. You are 18 years of age or older
C. You are a female
D. You meet ONE of the following:
    1. Therapy is prescribed by or in consultation with an Infectious Disease (ID) specialist (a doctor who specializes in the treatment of infections)
    2. Therapy is a continuation of care from an inpatient setting
    3. You meet ALL of the following:
        a. There is a culture (a type of laboratory test) that shows your infection is caused by a multidrug-resistant (other medications did not work well) bacteria
        b. Pivya will work against the bacteria from the culture
        c. The bacteria is resistant (other medication did not work well), or you have a contraindication to (harmful for you to use) other beta-lactams medications (such as cefdinir, cefaclor), fluoroquinolone medications (such as ciprofloxacin, levofloxacin), cephalosporins, penicillins, nitrofurantoin, and sulfamethoxazole/trimethoprim medications

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pivya.

REFERENCES

Pivya [Prescribing Information]. Florham Park, NJ: UTILITY therapeutics Ltd; April 2024.

Created: 11/24
Effective: 02/09/26 Client Approval: 01/26 P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PLASMINOGEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PLASMINOGEN, HUMAN-TVMH	RYPLAZIM	47437		GPI-10 (8540005070)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia) (ICD-10 E88.02)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PLASMINOGEN (Ryplazim)** requires the following rule(s) be met for approval:
   A. You have plasminogen deficiency type 1 (hypoplasminogenemia: a type of genetic condition)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ryplazim.

REFERENCES

Ryplazim [Prescribing Information]. Fort Lee, NJ: Kedrion Biopharma, Inc.; May 2024.

Created: 01/22
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/22

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PLERIXAFOR (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PLERIXAFOR	MOZOBIL, PLERIXAFOR	36021		GPI-10 (8250206000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with filgrastim or its biosimilars (e.g., Neupogen, Nivestym)
   - The requested medication will be used to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation

   If yes, **approve for 1 month by HICL or GPI-10 with a quantity limit of #9.6mL for one fill.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of multiple myeloma (MM) and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with filgrastim or its biosimilars (e.g., Neupogen, Nivestym)
   - The requested medication will be used to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation

   If yes, **approve for 1 month by HICL or GPI-10 with a quantity limit of #9.6mL for one fill.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PLERIXAFOR (Mozobil)** requires you meet the following rule(s) for approval:
   A. You have ONE of the following:
      1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
      2. Multiple myeloma (MM: a type of blood cancer)
   B. The requested medication will be used in combination with filgrastim or its biosimilars (such as Neupogen, Nivestym)
   C. The requested medication will be used to mobilize hematopoietic stem cells to the peripheral blood for collection (a type of blood cell is stimulated to be collected from your blood) followed by autologous stem cell transplantation (a type of procedure to replace damaged bone marrow with your own healthy blood-forming cells)

   (Denial text continued on the next page)

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PLERIXAFOR (NSA)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mozobil.

REFERENCES

Mozobil [Prescribing Information]. Cambridge, MA: Genzyme Corporation; September 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/09/23
Created: 02/09
Client Approval: 09/23
P&T Approval: 04/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PLOZASIRAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PLOZASIRAN SODIUM	REDEMPLO	51006		GPI-10 (3090627030)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of familial chylomicronemia syndrome (FCS) (ICD-10 E78.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Redemplo will be used as an adjunct therapy to diet
   - Redemplo will NOT be used concurrently with another agent (e.g., Tryngolza [olezarsen]) for the treatment of FCS

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient's FCS diagnosis been confirmed with **ONE** of the following criteria?
   - Genetic testing
   - History of fasting triglycerides of at least 1000 mg/dL on repeated testing (for at least 3 prior occasions) AND a history of recurrent acute pancreatitis that is not caused by alcohol or cholelithiasis, a history of hospitalization for severe abdominal pain without other explainable cause, or a family history of hypertriglyceridemia-induced pancreatitis

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PLOZASIRAN (Redemplo)** requires the following rule(s) be met for approval:
   A. You have familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
   B. You are 18 years of age or older
   C. You will use Redemplo as an adjunct (add-on) therapy to diet
   D. You will NOT use Redemplo concurrently (at the same time) with another medication (such as Tryngolza [olezarsen]) for the treatment of familial chylomicronemia syndrome (FCS: a type of rare genetic condition)

   (Initial denial text continued on next page)

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PLOZASIRAN

INITIAL CRITERIA (CONTINUED)

E. Your familial chylomicronemia syndrome (FCS: a type of rare genetic condition) has been confirmed with ONE of the following:
   1. Genetic testing (a type of lab test)
   2. History of fasting triglycerides (a type of fat) of at least 1000 mg/dL on repeated testing (for at least 3 prior occasions) AND a history of recurrent acute pancreatitis (short-term inflammation of the pancreas) that is not caused by alcohol or cholelithiasis (hard, pebble-like stones that form inside gallbladder), a history of hospitalization for severe abdominal pain without other explainable cause, or a family history of hypertriglyceridemia-induced pancreatitis (high levels of fat in the blood due to pancreas inflammation)

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PLOZASIRAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of familial chylomicronemia syndrome (FCS) (ICD-10 E78.3) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit as demonstrated by a reduction in triglyceride levels
   - Redemplo will NOT be used concurrently with another agent (e.g., Tryngolza [olezarsen]) for the treatment of FCS

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PLOZASIRAN (Redemplo)** requires the following rule(s) be met for renewal:
   A. You have familial chylomicronemia syndrome (FCS: a type of rare genetic condition)
   B. You have experienced a clinical benefit as shown by a reduction (decrease) in triglyceride (a type of fat) levels
   C. You will NOT use Redemplo concurrently (at the same time) with another medication (such as Tryngolza [olezarsen]) for the treatment of familial chylomicronemia syndrome (FCS: a type of rare genetic condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Redemplo.

REFERENCES

Redemplo [Prescribing Information]. Pasadena, CA: Arrowhead Pharmaceuticals, Inc.; November 2025.

Created: 12/25
Effective: 08/28/26 Client Approval: 08/26 DMC Approval: 08/25/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POLATUZUMAB VEDOTIN-PIIQ (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POLATUZUMAB VEDOTIN-PIIQ	POLIVY	45781		GPI-10 (2135486030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with bendamustine and a rituximab product
   - The patient has had at least two prior therapies (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone], tafasitamab with lenalidomide)
   - The patient is not a candidate for autologous hematopoietic stem cell transplant

   If yes, **approve for 6 months by HICL or GPI-10 for #1 fill per 21 days with a maximum of #6 fills.**

   If no, continue to #2.

2. Does that patient have a diagnosis of previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP)

   If yes, **approve for 6 months by HICL or GPI-10 for #1 fill per 21 days with a maximum of #6 fills.**
   If no, continue to #3.

3. Does that patient have a diagnosis of previously untreated high-grade B-cell lymphoma (HGBL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an International Prognostic Index score of 2 or greater
   - The requested medication will be used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP)

   If yes, **approve for 6 months by HICL or GPI-10 for #1 fill per 21 days with a maximum of #6 fills.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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POLATUZUMAB VEDOTIN-PIIQ (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **POLATUZUMAB VEDOTIN-PIIQ (Polivy)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Relapsed (returned) or refractory (resistant to treatment) diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), not otherwise specified
   2. Previously untreated diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), not otherwise specified
   3. Previously untreated high-grade B-cell lymphoma (HGBL: an aggressive type of blood cancer)

B. If you have relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, approval also requires:
   1. You are 18 years of age or older
   2. The requested drug will be used in combination with bendamustine and a rituximab product (type of cancer drug)
   3. You have had at least two prior therapies (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone], tafasitamab with lenalidomide)
   4. You are not a candidate for an autologous hematopoietic stem cell transplant (cells transferred from your own body)

C. If you have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified, approval also requires:
   1. You are 18 years of age or older
   2. The requested drug will be used in combination with a rituximab product (type of cancer drug), cyclophosphamide, doxorubicin, and prednisone (R-CHP)

D. If you have previously untreated high-grade B-cell lymphoma (HGBL), approval also requires:
   1. You are 18 years of age or older
   2. You have International Prognostic Index (a tool used to determine the likely cause of a disease) score of 2 or greater
   3. The requested drug will be used in combination with a rituximab product (type of cancer drug), cyclophosphamide, doxorubicin, and prednisone (R-CHP)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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POLATUZUMAB VEDOTIN-PIIQ (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Polivy.

REFERENCES

Polivy [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; April 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 05/22/23
Created: 08/19
Client Approval: 05/23
P&T Approval: 07/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POMALIDOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POMALIDOMIDE	POMALYST, POMALIDOMIDE	39996		GPI-10 (2145008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) (ICD-10 Group C90.0) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The requested medication will be used in combination with dexamethasone
- The patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib])

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.**
If no, continue to #2.

2. Does the patient have a diagnosis of Kaposi sarcoma (KS) (ICD-10 Group C46) **AND** meet the following criterion?
- The patient is 18 years of age or older

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
- The patient has AIDS-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART)
- The patient is HIV-negative

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **POMALIDOMIDE (Pomalyst)** requires the following rule(s) be met for approval:
A. You have ONE of the following:
   1. Multiple myeloma (MM: a type of blood cancer)
   2. Kaposi sarcoma (KS: a type of cancer in the lining of blood and lymph vessels)

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POMALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

B. If you have multiple myeloma, approval also requires:
1. You are 18 years of age or older
2. The requested medication will be used in combination with dexamethasone
3. You have tried at least two prior treatments including Revlimid (lenalidomide) and a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib], Ninlaro [ixazomib])

C. If you have Kaposi sarcoma, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. You have acquired immunodeficiency syndrome (AIDS: a type of immune system disorder caused by virus infection)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART: medications used to treat human immunodeficiency virus [HIV: a type of immune disorder])
   b. You are human immunodeficiency virus (HIV)-negative

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Pomalyst.

REFERENCES
Pomalyst [Prescribing Information]. Summit, NJ: Celgene Corporation; March 2023.

Created: 02/13
Effective: 02/28/26 Client Approval: 02/26 P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PONATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PONATINIB HCL	ICLUSIG	39859		GPI-10 (2153187510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic myeloid leukemia (CML) (ICD-10 Groups C92.1, C92.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a mutational analysis prior to initiation AND Iclusig is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient have T315I-positive CML (chronic phase, accelerated phase, or blast phase)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have chronic phase (CP) chronic myeloid leukemia (CML) **AND** meet the following criterion?
   - The patient has a resistance or intolerance to at least TWO prior kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Does the patient have accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML) **AND** meet the following criterion?
   - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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PONATINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (ICD-10 Group C91.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer is positive for the T315I mutation
   - There are no other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] indicated for the patient
   - The patient is newly diagnosed (e.g., starting or previously started Iclusig treatment at the time of diagnosis) AND Iclusig will be used in combination with chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PONATINIB (Iclusig)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Chronic myeloid leukemia (CML: type of blood cell cancer)
      2. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cell cancer)

   B. If you have chronic myeloid leukemia, approval also requires:
      1. You are 18 years of age or older
      2. You had a mutational analysis (a type of test) before starting therapy AND Iclusig is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region- Abelson murine leukemia 1; a type of abnormal gene) profile
      3. You meet ONE of the following:
         a. You have T315I-positive (a genetic mutation) CML (chronic phase, accelerated phase, or blast phase)
         b. You have chronic phase CML AND have a resistance to or are not able to safely use at least TWO prior kinase inhibitor treatments [such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)]
         c. You have accelerated phase or blast phase CML AND there are no other kinase inhibitors [such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib),
         Gleevec (imatinib)] that can be used for your disease

(Denial text continued on next page)

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PONATINIB

GUIDELINES FOR USE (CONTINUED)

C. If you have Philadelphia chromosome positive acute lymphoblastic leukemia, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your cancer is positive for the T315I mutation (a type of abnormal gene)
   b. There are no other kinase inhibitors (such as Tasigna [nilotinib], Sprycel [dasatinib], Bosulif [bosutinib], Gleevec [imatinib]) that can be used for the treatment of your disease
   c. You are newly diagnosed (such as you are starting or previously started Iclusig treatment at the time your condition was identified) AND Iclusig will be used in combination with chemotherapy

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Iclusig.

REFERENCES
Iclusig [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2024.

Created: 01/13
Effective: 08/11/25 Client Approval: 07/25 P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PONESIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PONESIMOD	PONVORY	47221		GPI-10 (6240706000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Zeposia (ozanimod), fingolimod (Gilenya), dimethyl fumarate (Tecfidera), Vumerity (diroximel fumarate), Mayzent (siponimod)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ANY** of the following contraindications to Ponvory?
   - Within the past 6 months, experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   - A presence of Mobitz Type II 2nd degree or 3rd degree AV block, sick sinus syndrome, or sino- atrial block, unless the patient has a functioning pacemaker

   If yes, do not approve.
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PONESIMOD (Ponvory)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Zeposia (ozanimod), fingolimod (Gilenya), dimethyl fumarate (Tecfidera), Vumerity (diroximel fumarate), Mayzent (siponimod)

   (Denial text continued on next page)

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PONESIMOD

GUIDELINES FOR USE (CONTINUED)

D. You do NOT have any of the following contraindications to (harmful for you to use) Ponvory:
   1. Within the past 6 months, experienced a myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (TIA: short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   2. A presence of Mobitz Type II 2nd degree or 3rd degree AV block, sick sinus syndrome, or sino-atrial block (types of irregular heartbeats), unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ponvory.

REFERENCES

Ponvory [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; June 2024.

Created: 03/21
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PORFIMER

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PORFIMER SODIUM	PHOTOFRIN	11790		GPI-10 (2170707010)	

GUIDELINES FOR USE

1. Is the requested medication being used for the reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC)?

   If yes, **approve once by HICL or GPI-10.**
   If no, continue to #2.

2. Is the requested medication being used for the treatment of microinvasive endobronchial non-small cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated?

   If yes, **approve once by HICL or GPI-10.**
   If no, continue to #3.

3. Is the requested medication being used for the palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy?

   If yes, **approve once by HICL or GPI-10.**
   If no, continue to #4.

4. Is the requested medication being used for the ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy?

   If yes, **approve once by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PORFIMER (Photofrin)** requires that the drug is being used for one of the following conditions:
   A. The reduction of blockage and palliation of symptoms (treatment focused on relief from the symptoms and stress of a serious illness) in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC) or,
   B. Treatment of microinvasive endobronchial non-small cell lung cancer (a type of lung cancer that involves airway blockage) where surgery and radiation therapy cannot be used; or
   C. Helping to lessen your symptoms with completely obstructing or partially obstructing esophageal cancer, where in the opinion of your physician, you cannot be treated with Nd:YAG laser therapy (a high intensity laser that can be used to remove cancer) or,

   (Denial text continued on next page)

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PORFIMER

GUIDELINES FOR USE (CONTINUED)

D. The ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy (removal of precancerous cells of the esophagus and you did not have surgical treatment for esophageal cancer)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Photofrin.

REFERENCES

Photofrin [Prescribing Information]. Bannockburn, IL: Pinnacle Biologics, Inc.; December 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/13
Client Approval: 04/20
P&T Approval: 11/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POSACONAZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POSACONAZOLE	NOXAFIL, POSACONAZOLE	33461		GPI-10 (1140706000)	ROUTE = ORAL

GUIDELINES FOR USE

1. Is the request for continuation of therapy after the patient was started on posaconazole in the hospital?

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #2.

2. Is the request for the treatment of invasive aspergillosis (ICD-10 B44.0)?

   If yes, continue to #3.
   If no, continue to #5.

3. Is the request for posaconazole (Noxafil) tablets **AND** the patient meets the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 12 weeks by GPID or GPI-14.**
   If no, continue to #4.

4. Is the request for posaconazole (Noxafil) PowderMix and the patient meets **ALL** of the following criteria?
   - The patient is 2 to 17 years of age
   - The patient has a contraindication to or is unable to swallow tablets

   If yes, **approve for 12 weeks by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for prophylaxis of invasive Aspergillus or Candida infections **AND** the patient meets the following criterion?
   - The patient is at high risk of developing these infections due to being severely immunocompromised (e.g., hematopoietic stem cell transplant [HSCT] recipients with graft-versus-host disease [GVHD], hematologic malignancy with prolonged neutropenia from chemotherapy)

   If yes, continue to #6.
   If no, continue to #9.

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

6. Is the request for posaconazole (Noxafil) tablets **AND** the patient meets the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #7.

7. Is the request for posaconazole (Noxafil) oral suspension and the patient meets **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient has a contraindication to or is unable to swallow tablets

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #8.

8. Is the request for posaconazole (Noxafil) PowderMix and the patient meets **ALL** of the following criteria?
   - The patient is 2 to 17 years of age
   - The patient has a contraindication to or is unable to swallow tablets

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have a diagnosis of oropharyngeal candidiasis (OPC) (ICD-10 B37.0) and meet **ALL** of the following criteria?
   - The patient is 13 years of age or older
   - The patient had a trial of or contraindication to ONE preferred agent: fluconazole, itraconazole
   - The request is for posaconazole (Noxafil) oral suspension

   If yes, **approve for 3 months by GPID or GPI-14.**
   If no, continue to #10.

10. Does the patient have a diagnosis of esophageal candidiasis (ICD-10 B37.81) and meet **ALL** of the following criteria?
    - The patient is 13 years of age or older
    - The patient had a trial of or contraindication to TWO of the following clinical standard of care agents: fluconazole, itraconazole solution, voriconazole

    If yes, **approve for 3 months by GPID or GPI-14.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **POSACONAZOLE (Noxafil)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Continuation of therapy after hospital discharge
   2. Treatment of invasive aspergillosis (type of fungal infection)
   3. Prophylaxis (prevention) of invasive aspergillus or candida infections (types of fungal infection)
   4. Oropharyngeal candidiasis (OPC: fungal infection of the throat)
   5. Esophageal candidiasis (fungal infection in the tube connecting the throat and stomach)

B. If the request is for treatment of invasive aspergillosis, approval also requires:
   1. If the request is for posaconazole (Noxafil) tablets, approval also requires you meet the following:
      a. You are 2 years of age or older
   2. If the request is for posaconazole (Noxafil) PowderMix, approval also requires you meet ALL of the following:
      a. You are 2 to 17 years of age
      b. You have a contraindication to (harmful for you to use) or are unable to swallow tablets

C. If the request is for prophylaxis of invasive aspergillus or candida infections, approval also requires:
   1. You are at high risk of developing these infections due to being severely immunocompromised (such as hematopoietic stem cell transplant (HSCT: bone marrow transplant] recipients with graft-versus-host disease [GVHD: a type of immune disorder], hematologic malignancies [cancer affecting the blood] with prolonged neutropenia [low levels of a type of white blood cell] from chemotherapy [cancer treatment])
   2. If the request is for posaconazole (Noxafil) tablets, approval also requires you meet the following:
      a. You are 2 years of age or older
   3. If the request is for posaconazole (Noxafil) oral suspension, approval also requires you meet ALL of the following:
      a. You are 13 years of age or older
      b. You have a contraindication to (harmful for you to use) or are unable to swallow tablets
   4. If the request is for posaconazole (Noxafil) PowderMix, approval also requires you meet ALL of the following:
      a. You are 2 to 17 years of age
      b. You have a contraindication to (harmful for you to use) or are unable to swallow tablets

(Denial text continued on next page)

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POSACONAZOLE

GUIDELINES FOR USE (CONTINUED)

D. If the request is for oropharyngeal candidiasis, approval also requires:
1. You are 13 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) ONE preferred medication: fluconazole, itraconazole
3. You are requesting posaconazole (Noxafil) oral suspension

E. If the request is for esophageal candidiasis, approval also requires:
1. You are 13 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) TWO of the following clinical standard of care medications: fluconazole, itraconazole solution, voriconazole

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Noxafil.

REFERENCES
Noxafil [Prescribing Information]. Rahway, NJ: Merck & Co., Inc.; January 2026.

Created: 11/07
Effective: 05/28/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

POZELIMAB-BBFG (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
POZELIMAB-BBFG	VEOPOZ	49162		GPI-10 (8580507015)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease, **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **POZELIMAB-BBFG (Veopoz)** requires the following rule(s) be met for approval:
   A. You have CD55-deficient protein-losing enteropathy (PLE, also known as CHAPLE disease [a rare genetic disorder])
   B. You are 1 year of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Veopoz.

REFERENCES

Veopoz [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
Client Approval: 11/23
P&T Approval: 10/23

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PRALATREXATE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PRALATREXATE	FOLOTYN, PRALATREXATE	36644		GPI-10 (2130005400)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PRALATREXATE (Folotyn)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory peripheral T-cell lymphoma (PTCL: a type of blood cancer that has returned or did not fully respond to treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Folotyn.

REFERENCES

Folotyn [Prescribing Information]. East Windsor, NJ: Acrotech Biopharma LLC; September 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 01/01/23
Created: 08/16
Client Approval: 11/22
P&T Approval: 08/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PRALSETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PRALSETINIB	GAVRETO	46818		GPI-10 (2153575000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a *RET* (rearranged during transfection) fusion-positive tumor, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has a *RET* (rearranged during transfection) fusion-positive tumor
   - The patient requires systemic therapy
   - The patient is radioactive iodine-refractory (if radioactive iodine is appropriate)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PRALSETINIB (Gavreto)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
      2. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)

   B. If you have metastatic non-small cell lung cancer, approval also requires:
      1. You are 18 years of age or older
      2. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor, as detected by a Food and Drug Administration (FDA)-approved test

   (Denial text continued on next page)

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PRALSETINIB

GUIDELINES FOR USE (CONTINUED)

C. If you have advanced or metastatic thyroid cancer, approval also requires:
1. You are 12 years of age or older
2. You have a rearranged during transfection (*RET*) fusion-positive (a type of gene mutation) tumor
3. You need systemic therapy (treatment that targets the entire body)
4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is an appropriate treatment option)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Gavreto.

REFERENCES
Gavreto [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2024.

Created: 10/20
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PREGABALIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PREGABALIN	LYRICA, PREGABALIN		32359	GPI-14 (72600057002020)	

GUIDELINES FOR USE

1. Does the patient have a contraindication to or is the patient unable to swallow generic pregabalin capsules?

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PREGABALIN (Lyrica)** requires the following rule(s) be met for approval:
   A. You have a contraindication to (harmful for you to use) or are unable to swallow generic pregabalin capsules

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lyrica.

REFERENCES

Lyrica [Prescribing Information]. New York, NY: Pfizer, Inc; June 2020.

Created: 05/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PYRIMETHAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PYRIMETHAMINE	DARAPRIM, PYRIMETHAMINE	04150		GPI-10 (1300004000)	ROUTE=ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient being treated for acute toxoplasmosis (ICD-10 Group B58) **AND** meets the following criterion?
   - Therapy is prescribed by or in consultation with an infectious disease specialist

   If yes**, approve for 6 weeks by HICL or GPI-10. Please enter two authorizations as follows:**
   - **Approve one fill for #8 per day.**
   - **Approve for 6 weeks with a quantity limit of #3 per day.**

   If no, continue to #2.

2. Is the patient being treated for chronic maintenance of toxoplasmosis (ICD-10 Group B58) and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an infectious disease specialist
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient has successfully completed treatment for acute toxoplasmosis for at least 6

   weeks If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**

   If no, continue to #3.

3. Is the patient being treated for primary prophylaxis of toxoplasmosis and meets **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an infectious disease specialist
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient had a trial of or has a contraindication to the clinical standard of care agent: Bactrim (SMX/TMP)
   - The patient is positive for *Toxoplasma gondii* IgG
   - The patient has a CD4 count of less than 100 cells/mm(3)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, continue to #4.

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PYRIMETHAMINE

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of congenital toxoplasmosis (ICD-10 P37.1) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a neonatologist or pediatric infectious disease specialist

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for approval:
   A. The request is ONE of the following:
      1. Acute (short-term) treatment of toxoplasmosis (a type of parasite infection)
      2. Chronic (long-term) maintenance therapy for toxoplasmosis
      3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
      4. Congenital toxoplasmosis (unborn baby infected with parasite from the mother)

   B. If you are being treated for acute toxoplasmosis, approval also requires:
      1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor that specializes in treating infections)

   C. If you are being treated for chronic maintenance for toxoplasmosis, approval also requires:
      1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor that specializes in treating infections)
      2. You are also infected with human immunodeficiency virus (HIV: an immune system disease caused by a virus)
      3. You have successfully completed treatment for acute toxoplasmosis for at least 6 weeks

   D. If you are being treated for primary prophylaxis of toxoplasmosis, approval also requires:
      1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor that specializes in treating infections)
      2. You are also infected with human immunodeficiency virus (HIV: an immune system disease caused by a virus)
      3. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: Bactrim (sulfamethoxazole-trimethoprim)
      4. You tested positive for *Toxoplasma gondii* (a type of parasite) Immunoglobulins (IgG) (you had a current or past infection with *Toxoplasma gondii)*
      5. Your CD4 count (a type of lab test) is less than 100 cells/mm(3)

   E. If you have congenital toxoplasmosis, approval also requires:
      1. Therapy is prescribed by or in consultation with a neonatologist (doctor that specializes in sick and premature newborn infants) or pediatric infectious disease specialist (a doctor that specializes in treating infections in children and adolescents)

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PYRIMETHAMINE

RENEWAL CRITERIA

NOTE: For the diagnosis of congenital toxoplasmosis, please refer to Initial Criteria section.

1. Is the patient being treated for acute toxoplasmosis (ICD-10 Group B58) **AND** meets the following criterion?
   - The patient has persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)

   If yes, **approve for 6 weeks by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, continue to #2.

2. Is the patient being treated for chronic maintenance of toxoplasmosis (ICD-10 Group B58) OR primary prophylaxis of toxoplasmosis and meets **ALL** of the following criteria?
   - The patient is infected with human immunodeficiency virus (HIV)
   - The patient has a CD4 count of less than 200 cells/mm(3)
   - The patient is currently taking ART (anti-retroviral therapy)

   If yes, **approve for 6 months by HICL or GPI-10 as follows:**
   - **Chronic maintenance of toxoplasmosis: #2 per day.**
   - **Primary prophylaxis of toxoplasmosis: #3 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for renewal:
   A. The request is ONE of the following:
      1. Acute (short-term) treatment of toxoplasmosis (a type of parasite infection)
      2. Chronic (long-term) maintenance therapy for toxoplasmosis
      3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)

   B. If you are being treated for acute toxoplasmosis, renewal also requires:
      1. You have persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)

   C. If you are being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis for toxoplasmosis, renewal also requires:
      1. You are also infected with human immunodeficiency virus (HIV: an immune system disease caused by a virus)
      2. Your CD4 count (a type of lab test) is less than 200 cells/mm(3)
      3. You are currently taking anti-retroviral therapy (ART: medications that treat HIV)

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PYRIMETHAMINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daraprim.

REFERENCES

Daraprim [Prescribing Information]. New York, NY: Vyera Pharmaceuticals LLC., August 2017.

Created: 10/15
Effective: 07/29/26 Client Approval: 07/26 P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

QUIZARTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
QUIZARTINIB DIHYDROCHLORIDE	VANFLYTA	49083		GPI-10 (2153304710)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia (AML) (ICD-10 Group C92.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is newly diagnosed (e.g., starting or previously started Vanflyta treatment at the time of diagnosis)
   - The patient's cancer is FLT3 internal tandem duplication (ITD)-positive, as detected by a Food and Drug Administration (FDA)-approved test

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Vanflyta be used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) for induction therapy, followed by use with cytarabine as consolidation therapy?

   If yes, **approve all strengths for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **17.7 mg: #28 per fill for a total of 6 fills.**
   - **26.5 mg: #14 per fill for a total of 6 fills.**

   If no, continue to #3.

3. Will Vanflyta be used as maintenance monotherapy following consolidation chemotherapy?

   If yes, **approve for 34 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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QUIZARTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **QUIZARTINIB (Vanflyta)** requires the following rule(s) be met for approval:

A. You have acute myeloid leukemia (AML: a type of blood and bone marrow cancer)
B. You are 18 years of age or older
C. You are newly diagnosed (such as you are starting or previously started Vanflyta treatment at the time your condition was identified)
D. Your cancer is FMS-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD: a type of mutation) positive, as detected by a Food and Drug Administration (FDA)-approved test
E. You meet ONE of the following:
    1. Vanflyta will be used in combination with a standard cytarabine and anthracycline (such as daunorubicin, idarubicin) as induction therapy (a type of therapy to treat cancer), followed by use with cytarabine as consolidation therapy (type of therapy to treat cancer)
    2. Vanflyta will be used as maintenance monotherapy (one drug treatment) following consolidation chemotherapy

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vanflyta.

REFERENCES

Vanflyta [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; June 2024.

Created: 11/23
Effective: 08/11/25 Client Approval: 07/25 P&T Approval: 10/23

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RAMUCIRUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RAMUCIRUMAB	CYRAMZA	41109		GPI-10 (2133507000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic gastric cancer or gastro-esophageal junction (GEJ) adenocarcinoma and meet **ALL** of the following criteria?
   - The requested medication will be used as a single agent or in combination with paclitaxel
   - The patient has experienced disease progression on or after prior fluoropyrimidine-containing chemotherapy (examples include fluorouracil [5-FU], capecitabine, floxuridine) **OR** platinum-containing chemotherapy (examples include cisplatin, oxaliplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with docetaxel
   - The patient has experienced disease progression on or after platinum-based chemotherapy (cisplatin, oxaliplatin, carboplatin) **OR** if the patient has an EGFR or ALK genomic tumor aberration, there is disease progression on an FDA-approved therapy for these aberrations (examples include Tarceva, Gilotrif, Xalkori, or Zykadia) prior to receiving Cyramza

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with erlotinib as first-line treatment
   - The tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #4.

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RAMUCIRUMAB (NSA)

GUIDELINE FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic colorectal cancer and meet **ALL** of the following criteria?
   - The requested medication will be used in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil)
   - The patient has experienced disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (such as 5-fluorouracil or capecitabine)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of hepatocellular carcinoma and meet **ALL** of the following criteria?
   - The requested medication will be used as a single agent
   - Patient has an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL
   - Patient has been treated with sorafenib (Nexavar)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RAMUCIRUMAB (Cyramza)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Advanced or metastatic (cancer that has spread to other parts of the body), gastric cancer or gastro-esophageal junction adenocarcinoma (cancer of the stomach or caner of the esophagus [tube that connects mouth and stomach])
      2. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of your body)
      3. Metastatic colorectal cancer (type of rcolon or rectum cancer that has spread to other parts of the body)
      4. Hepatocellular carcinoma (type of liver cancer)

   B. If you have advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, approval also requires:
      1. The requested medication will be used as a single agent or in combination with paclitaxel
      2. You have experienced disease progression (disease has worsened) on or after prior fluoropyrimidine-containing chemotherapy (examples include fluorouracil [5-FU], capecitabine, floxuridine) OR platinum-containing chemotherapy (examples include cisplatin, oxaliplatin, carboplatin)

   (Denial text continued on next page)

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RAMUCIRUMAB (NSA)

GUIDELINE FOR USE (CONTINUED)

C. If you have metastatic non-small cell lung cancer (NSCLC), approval also requires ONE of the following:

1. The requested medication will be used in combination with docetaxel and you meet ONE of the following:
   a. You have experienced disease progression (disease has worsened) on or after platinum-based chemotherapy (cisplatin, oxaliplatin, carboplatin)
   b. You have an epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK : type of enzyme) genomic tumor abnormality AND your disease has gotten worse on an Food and Drug Administration (FDA)-approved therapy (examples include Tarceva, Gilotrif, Xalkori, or Zykadia) prior to receiving Cyramza
2. The requested medication will be used in combination with erlotinib as first-line treatment AND your tumors have epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 (L858R) substitution mutations

D. If you have metastatic colorectal cancer, approval also requires:

1. The requested medication will be used in combination with FOLFIRI (drug combination of irinotecan, folinic acid, and 5-fluorouracil)
2. You have experienced disease progression (disease has worsened) on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (such as 5-fluorouracil or capecitabine)

E. If you have hepatocellular carcinoma, approval also requires:

1. The requested medication will be used as a single agent
2. You have an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL
3. You have been treated with sorafenib (Nexavar)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cyramza.

REFERENCES

Cyramza [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; June 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 04/14
Client Approval: 06/20
P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RANIBIZUMAB-EQRN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RANIBIZUMAB-EQRN	CIMERLI		52665 52664	GPI-14 (86655060302012, 86655060302020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - Cimerli will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve Cimerli 0.5mg for 4 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - Cimerli will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Vabysmo [faricimab-svoa])

   If yes, **approve Cimerli 0.5mg for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - Cimerli will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Vabysmo [faricimab-svoa])

   If yes, **approve Cimerli 0.3mg for 4 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #4.

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RANIBIZUMAB-EQRN

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - Cimerli will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Susvimo [ranibizumab])

   If yes, **approve Cimerli 0.3mg for 4 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of myopic choroidal neovascularization (mCNV) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist

   If yes, **approve Cimerli 0.5mg for 3 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RANIBIZUMAB-EQRN (Cimerli)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
      2. Macular edema following retinal vein occlusion (RVO: a type of eye condition)
      3. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
      4. Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
      5. Myopic choroidal neovascularization (mCNV: a type of eye condition)

   (Initial denial text continued on next page)

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RANIBIZUMAB-EQRN

INITIAL CRITERIA (CONTINUED)

B. If you have neovascular (wet) age-related macular degeneration, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

C. If you have macular edema following retinal vein occlusion, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

D. If you have diabetic macular edema, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

E. If you have diabetic retinopathy, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab])

F. If you have myopic choroidal neovascularization, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RANIBIZUMAB-EQRN

RENEWAL CRITERIA

NOTE: For the diagnosis of myopic choroidal neovascularization (mCNV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Cimerli will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve Cimerli 0.5mg for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Cimerli will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Vabysmo [faricimab-svoa])

   If yes, **approve Cimerli 0.5mg for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Cimerli will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Vabysmo [faricimab-svoa])

   If yes, **approve Cimerli 0.3mg for 12 months by GPID or GPI-14 with quantity limit of #0.1mL per 28 days.**

   If no, continue to #4.

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RANIBIZUMAB-EQRN

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Cimerli will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Susvimo [ranibizumab])

   If yes, **approve Cimerli 0.3mg for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RANIBIZUMAB-EQRN (Cimerli)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
      2. Macular edema following retinal vein occlusion (RVO: a type of eye condition)
      3. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
      4. Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

   B. If you have neovascular (wet) age-related macular degeneration, renewal also requires:
      1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
      2. You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

   C. If you have macular edema following retinal vein occlusion, renewal also requires:
      1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
      2. You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. If you have diabetic macular edema, renewal also requires:
1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
2. You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

E. If you have diabetic retinopathy, renewal also requires:
1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
2. You will NOT use Cimerli concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cimerli and Lucentis.

REFERENCES

Cimerli [Prescribing Information]. Redwood City, CA: Coherus BioSciences, Inc.; May 2024.
Lucentis [Prescribing Information]. South San Francisco, CA: Genentech, Inc; February 2024.

Created: 09/22
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RANIBIZUMAB-LUCENTIS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RANIBIZUMAB	LUCENTIS	33861		GPI-10 (8665506000)	BRAND ≠ SUSVIMO

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
   - Lucentis will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve Lucentis 0.5mg for 4 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
   - Lucentis will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Vabysmo [faricimab-svoa])

   If yes, **approve Lucentis 0.5mg for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #3.

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RANIBIZUMAB-LUCENTIS

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
   - Lucentis will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Vabysmo [faricimab-svoa])

   If yes, **approve Lucentis 0.3mg for 4 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
   - Lucentis will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Susvimo [ranibizumab])

   If yes, **approve Lucentis 0.3mg for 4 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of myopic choroidal neovascularization (mCNV) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist

   If yes, **approve Lucentis 0.5mg for 3 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RANIBIZUMAB-LUCENTIS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RANIBIZUMAB-LUCENTIS** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
   2. Macular edema following retinal vein occlusion (RVO: a type of eye condition)
   3. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
   4. Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
   5. Myopic choroidal neovascularization (mCNV: a type of eye condition)

B. If you have neovascular (wet) age-related macular degeneration, approval also requires:
   1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
   3. You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

C. If you have macular edema following retinal vein occlusion, approval also requires:
   1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
   3. You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

D. If you have diabetic macular edema, approval also requires:
   1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
   3. You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

(Initial denial text continued on next page)

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RANIBIZUMAB-LUCENTIS

INITIAL CRITERIA (CONTINUED)

E. If you have diabetic retinopathy, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Byooviz (ranibizumab-nuna), Cimerli (ranibizumab-eqrn)
3. You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab])

F. If you have myopic choroidal neovascularization, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RANIBIZUMAB-LUCENTIS

RENEWAL CRITERIA

NOTE: For the diagnosis of myopic choroidal neovascularization (mCNV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Lucentis will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve Lucentis 0.5mg for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Lucentis will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Vabysmo [faricimab-svoa])

   If yes, **approve Lucentis 0.5mg for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Lucentis will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Vabysmo [faricimab-svoa])

   If yes, **approve Lucentis 0.3mg for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #4.

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RANIBIZUMAB-LUCENTIS

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Lucentis will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Susvimo [ranibizumab])

   If yes, **approve Lucentis 0.3mg for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RANIBIZUMAB-LUCENTIS** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
      2. Macular edema following retinal vein occlusion (RVO: a type of eye condition)
      3. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
      4. Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

   B. If you have neovascular (wet) age-related macular degeneration, renewal also requires:
      1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
      2. You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab], Beovu [brolucizumab-dbll])

   C. If you have macular edema following retinal vein occlusion, renewal also requires:
      1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
      2. You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. If you have diabetic macular edema, renewal also requires:
1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
2. You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

E. If you have diabetic retinopathy, renewal also requires:
1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
2. You will NOT use Lucentis concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Susvimo [ranibizumab])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lucentis.

REFERENCES

Lucentis [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2024.

Created: 05/14
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RANIBIZUMAB-NUNA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RANIBIZUMAB-NUNA	BYOOVIZ	47583		GPI-10 (8665506050)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - Byooviz will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - Byooviz will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Vabysmo [faricimab-svoa])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - Byooviz will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #4.

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RANIBIZUMAB-NUNA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - Byooviz will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab])

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of myopic choroidal neovascularization (mCNV) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RANIBIZUMAB-NUNA (Byooviz)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
      2. Macular edema following retinal vein occlusion (RVO: a type of eye condition)
      3. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
      4. Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)
      5. Myopic choroidal neovascularization (mCNV: a type of eye condition)

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

B. If you have neovascular (wet) age-related macular degeneration, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

C. If you have macular edema following retinal vein occlusion, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

D. If you have diabetic macular edema, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

E. If you have diabetic retinopathy, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])

F. If you have myopic choroidal neovascularization, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RANIBIZUMAB-NUNA

RENEWAL CRITERIA

NOTE: For the diagnosis of myopic choroidal neovascularization (mCNV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Byooviz will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of macular edema following retinal vein occlusion (RVO) (ICD-10 H34.9; Groups H34.81, H34.83) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Byooviz will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Vabysmo [faricimab-svoa])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Byooviz will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

   If no, continue to #4.

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RANIBIZUMAB-NUNA

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, and E08.39; Group E09.3 except E09.36, E09.37, and E09.39; Group E10.3 except E10.36, E10.37, and E10.39; Group E11.3 except E11.36, E11.37, and E11.39) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Byooviz will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.1mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RANIBIZUMAB-NUNA (Byooviz)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
      2. Macular edema following retinal vein occlusion (RVO: a type of eye condition)
      3. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
      4. Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

   B. If you have neovascular (wet) age-related macular degeneration, renewal also requires:
      1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
      2. You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

   C. If you have macular edema following retinal vein occlusion, renewal also requires:
      1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
      2. You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Vabysmo [faricimab-svoa])

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. If you have diabetic macular edema, renewal also requires:
1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
2. You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Beovu [brolucizumab-dbll], Eylea [aflibercept], Lucentis [ranibizumab])

E. If you have diabetic retinopathy, renewal also requires:
1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
2. You will NOT use Byooviz concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Byooviz and Lucentis.

REFERENCES

Byooviz [Prescribing Information]. Cambridge, MA: Biogen Inc.; October 2023.
Lucentis [Prescribing Information]. South San Francisco, CA: Genentech, Inc; February 2024.

Created: 06/22
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RANIBIZUMAB-SUSVIMO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RANIBIZUMAB, RANIBIZUMAB/INIT FILL NEEDLE	SUSVIMO		51414 52174	GPI-14 (86655060002040, 86655060002042)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - The patient has previously responded to at least TWO intravitreal injections of a VEGF inhibitor (e.g., Cimerli [ranibizumab-eqrn], Byooviz [ranibizumab-nuna])
   - Susvimo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for the treatment of nAMD

   If yes, **approve the requested medication for 6 months by GPID or GPI-14 with a quantity limit of #0.1mL per 6 months.**

   If no, continue to #2.

2. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - The patient has previously responded to at least TWO intravitreal injections of a VEGF inhibitor (e.g., Cimerli [ranibizumab-eqrn], Byooviz [ranibizumab-nuna])
   - Susvimo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve the requested medication for 6 months by GPID or GPI-14 with a quantity limit of #0.1mL per 6 months.**

   If no, continue to #3.

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RANIBIZUMAB-SUSVIMO

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, E08.39; Group E09.3 except E09.36, E09.37, E09.39; Group E10.3 except E10.36, E10.37, E10.39; Group E11.3 except E11.36, E11.37, E11.39) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist
   - The patient has previously responded to at least TWO intravitreal injections of a VEGF inhibitor (e.g., Cimerli [ranibizumab-eqrn], Byooviz [ranibizumab-nuna])
   - Susvimo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab])

   If yes, **approve the requested medication for 9 months by GPID or GPI-14 with a quantity limit of #0.1mL per 9 months.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RANIBIZUMAB (Susvimo)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
      2. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
      3. Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

   B. If you have neovascular (wet) age-related macular degeneration, approval also requires:
      1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
      2. You have previously responded to at least TWO intravitreal (into the eye) injections of a vascular endothelial growth factor (VEGF) inhibitor (such as Cimerli [ranibizumab-eqrn], Byooviz [ranibizumab-nuna])
      3. You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for the treatment of neovascular (wet) age-related macular degeneration

   (Initial denial text continued on next page)

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RANIBIZUMAB-SUSVIMO

INITIAL CRITERIA (CONTINUED)

C. If you have diabetic macular edema, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You have previously responded to at least TWO intravitreal (into the eye) injections of a vascular endothelial growth factor (VEGF) inhibitor (such as Cimerli [ranibizumab-eqrn], Byooviz [ranibizumab-nuna])
3. You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

D. If you have diabetic retinopathy, approval also requires:
1. Therapy is prescribed by or in consultation with an ophthalmologist (a type of eye doctor) or retina (a part of the eye) specialist
2. You have previously responded to at least TWO intravitreal (into the eye) injections of a vascular endothelial growth factor (VEGF) inhibitor (such as Cimerli [ranibizumab-eqrn], Byooviz [ranibizumab-nuna])
3. You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RANIBIZUMAB-SUSVIMO

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (nAMD) (ICD-10 Group H35.32) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Susvimo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for the treatment of nAMD

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 6 months.**

   If no, continue to #2.

2. Does the patient have a diagnosis of diabetic macular edema (DME) (ICD-10 E08.311, E08.321, E08.331, E08.341, E08.351, E08.37, E09.311, E09.321, E09.331, E09.341, E09.351, E09.37, E10.311, E10.321, E10.331, E10.341, E10.351, E10.37, E11.311, E11.321, E11.331, E11.341, E11.351, E11.37, E13.311, E13.321, E13.331, E13.341, E13.351, E13.37) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Susvimo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 6 months.**

   If no, continue to #3.

3. Does the patient have a diagnosis of diabetic retinopathy (DR) (ICD-10 Group E08.3 except E08.36, E08.37, E08.39; Group E09.3 except E09.36, E09.37, E09.39; Group E10.3 except E10.36, E10.37, E10.39; Group E11.3 except E11.36, E11.37, E11.39) and meet **ALL** of the following criteria?
   - The patient has maintenance or improvement of visual acuity
   - Susvimo will NOT be used concurrently with other intravitreal VEGF inhibitors (e.g., Eylea [aflibercept], Lucentis [ranibizumab])

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of #0.1mL per 9 months.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RANIBIZUMAB-SUSVIMO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RANIBIZUMAB (Susvimo)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Neovascular (wet) age-related macular degeneration (nAMD: a type of eye condition)
   2. Diabetic macular edema (DME: a type of eye condition caused by high blood sugar)
   3. Diabetic retinopathy (DR: a type of eye condition caused by high blood sugar)

B. If you have neovascular (wet) age-related macular degeneration, renewal also requires:
   1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
   2. You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll]) for the treatment of neovascular (wet) age-related macular degeneration

C. If you have diabetic macular edema, renewal also requires:
   1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
   2. You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab], Beovu [brolucizumab-dbll])

D. If you have diabetic retinopathy, renewal also requires:
   1. You have maintenance or improvement of visual acuity (vision clarity or sharpness)
   2. You will NOT use Susvimo concurrently (at the same time) with other intravitreal (into the eye) vascular endothelial growth factor (VEGF) inhibitors (such as Eylea [aflibercept], Lucentis [ranibizumab])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Susvimo.

REFERENCES

Susvimo [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; September 2025.

Created: 05/22
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RAVULIZUMAB-CWVZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RAVULIZUMAB-CWVZ	ULTOMIRIS	45548		GPI-10 (8580508020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC- HUS) (ICD-10 D59.31)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a hematologist
   - The patient has flow cytometry demonstrating at least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes) AND a PNH granulocyte clone size of at least 10 percent
   - Ultomiris will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for a total of 6 months by GPID or GPI-14 for the requested medication as follows:**
   - **For the 300mg/30mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #660mL per 28 days.**
     - **Maintenance dose: Approve for 5 months with a quantity limit of #360mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**
   - **For the 300mg/3mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #66mL per 28 days.**
     - **Maintenance dose: Approve for 5 months with a quantity limit of #36mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**
   - **For the 1,100mg/11mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #77mL per 28 days.**
     - **Maintenance dose: Approve for 5 months with a quantity limit of #44mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**

   If no, continue to #3.

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RAVULIZUMAB-CWVZ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39) **AND** meet the following criterion?
   - The patient is 1 month of age or older

   If yes, **approve for a total of 12 months by GPID or GPI-14 for the requested medication as follows:**
   - **For the 300mg/30mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #660mL per 28 days.**
     - **Maintenance dose: Approve for 11 months with a quantity limit of #360mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**
   - **For the 300mg/3mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #66mL per 28 days.**
     - **Maintenance dose: Approve for 11 months with a quantity limit of #36mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**
   - **For the 1,100mg/11mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #77mL per 28 days.**
     - **Maintenance dose: Approve for 11 months with a quantity limit of #44mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**

   If no, continue to #4.

4. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+)
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod- hyaluronidase-qvfc)
   - Ultomiris will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG

   If yes, continue to #5.
   If no, continue to #6.

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RAVULIZUMAB-CWVZ

INITIAL CRITERIA (CONTINUED)

5. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange

   If yes, **approve for a total of 6 months by GPID or GPI-14 for the requested medication as follows:**
   - **For the 300mg/30mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #660mL per 28 days.**
     - **Maintenance dose: Approve for 5 months with a quantity limit of #360mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**
   - **For the 300mg/3mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #66mL per 28 days.**
     - **Maintenance dose: Approve for 5 months with a quantity limit of #36mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**
   - **For the 1,100mg/11mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #77mL per 28 days.**
     - **Maintenance dose: Approve for 5 months with a quantity limit of #44mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ophthalmologist
   - The patient is positive for anti-aquaporin-4 (AQP4) antibodies
   - Ultomiris will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RAVULIZUMAB-CWVZ

INITIAL CRITERIA (CONTINUED)

7. Does the patient have at least **ONE** of the following core clinical characteristics?
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for a total of 12 months by GPID or GPI-14 for the requested medication as follows:**
   - **For the 300mg/30mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #660mL per 28 days.**
     - **Maintenance dose: Approve for 11 months with a quantity limit of #360mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**
   - **For the 300mg/3mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #66mL per 28 days.**
     - **Maintenance dose: Approve for 11 months with a quantity limit of #36mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**
   - **For the 1,100mg/11mL vial, enter BOTH of the following approvals:**
     - **Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of #77mL per 28 days.**
     - **Maintenance dose: Approve for 11 months with a quantity limit of #44mL per 8 weeks (start date is 3 weeks from the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RAVULIZUMAB-CWVZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   2. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
   3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   4. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

B. Ultomiris (ravulizumab-cwvz) is NOT being used for the treatment of hemolytic uremic syndrome related to Shiga toxin E. coli (a bacteria)

C. If you have paroxysmal nocturnal hemoglobinuria, approval also requires:
   1. You are 1 month of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   3. You have flow cytometry (a type of lab test) demonstrating at least 2 different GPI-protein deficiencies (you are missing a certain type of protein, such as CD55, CD59) on at least 2 cell lineages (types of cells, such as erythrocytes [red blood cells], granulocytes [a type of white blood cell]) AND a PNH granulocyte clone size of at least 10 percent
   4. You will NOT use Ultomiris concurrently (at the same time) with C5 complement inhibitor therapy (such as Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

D. If you have atypical hemolytic uremic syndrome, approval also requires:
   1. You are 1 month of age or older

(Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

E. If you have generalized myasthenia gravis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
3. You have a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+: a type of blood test that shows you have myasthenia gravis)
4. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
5. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
6. You have tried or have a contraindication to ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)
7. You will NOT use Ultomiris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
8. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
   b. You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)

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INITIAL CRITERIA (CONTINUED)

F. If you have neuromyelitis optica spectrum disorder (NMOSD), approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
3. You are positive for anti-aquaporin-4 (AQP4: a type of protein) antibodies
4. You will NOT use Ultomiris concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Soliris [eculizumab])
5. You have at least ONE of the following core clinical characteristics:
   a. Optic neuritis (a type of brain disorder)
   b. Acute myelitis (a type of brain disorder)
   c. Area postrema syndrome (a type of brain disorder)
   d. Acute brainstem syndrome (a type of brain disorder)
   e. Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
   f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RAVULIZUMAB-CWVZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) (ICD-10 D59.5) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase [LDH] and hemoglobin levels) compared to baseline
   - Ultomiris will NOT be used concurrently with C5 complement inhibitor therapy (e.g., Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (e.g., Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (e.g., Fabhalta [iptacopan])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested medication with the following quantity limits:**
   - **300mg/30mL vial: #360mL per 8 weeks.**
   - **300mg/3mL vial: #36mL per 8 weeks.**
   - **1,100mg/11mL vial: #44mL per 8 weeks.**

   If no, continue to #2.

2. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS) (ICD-10 D59.32, D59.39)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested medication with the following quantity limits:**
   - **300mg/30mL vial: #360mL per 8 weeks.**
   - **300mg/3mL vial: #36mL per 8 weeks.**
   - **1,100mg/11mL vial: #44mL per 8 weeks.**

   If no, continue to #3.

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RAVULIZUMAB-CWVZ

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient experienced a clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Ultomiris will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG

   If yes, **approve for 12 months by GPID or GPI-14 for the requested medication with the following quantity limits:**
   - **300mg/30mL vial: #360mL per 8 weeks.**
   - **300mg/3mL vial: #36mL per 8 weeks.**
   - **1,100mg/11mL vial: #44mL per 8 weeks.**

   If no, continue to #4.

4. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical benefit (reduction in relapse frequency compared to baseline or a decrease in NMOSD-related hospitalizations)
   - Ultomiris will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

   If yes, **approve for 12 months by GPID or GPI-14 for the requested medication with the following quantity limits:**
   - **300mg/30mL vial: #360mL per 8 weeks.**
   - **300mg/3mL vial: #36mL per 8 weeks.**
   - **1,100mg/11mL vial: #44mL per 8 weeks.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RAVULIZUMAB-CWVZ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare blood disorder)
   2. Atypical hemolytic uremic syndrome (aHUS: a rare blood disorder)
   3. Generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   4. Neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)

B. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
   1. You have experienced a clinical benefit (such as a reduction in the number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: a type of enzyme] levels and hemoglobin [Hgb: a type of protein in red blood cells] levels) compared to baseline (before treatment)
   2. You will NOT use Ultomiris concurrently (at the same time) with C5 complement inhibitor therapy (such as Soliris [eculizumab], Piasky [crovalimab-akkz]), C3 complement inhibitor therapy (such as Empaveli [pegcetacoplan]) or Factor B inhibitor therapy (such as Fabhalta [iptacopan])

C. If you have generalized myasthenia gravis, renewal also requires:
   1. You have experienced a clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   2. You will NOT use Ultomiris concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

D. If you have neuromyelitis optica spectrum disorder, renewal also requires:
   1. You have experienced a clinical benefit (reduction in relapse frequency compared to baseline [before treatment] or a decrease in NMOSD-related hospitalizations)
   2. You will NOT use Ultomiris concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Enspryng [satralizumab-mwge], Uplizna [inebilizumab-cdon], Soliris [eculizumab])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RAVULIZUMAB-CWVZ

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Review for Ultomiris.

REFERENCES
Ultomiris [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; September 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REGORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REGORAFENIB	STIVARGA	39665		GPI-10 (2153305000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (CRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine)
   - The patient has received previous treatment with an anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])

   If yes, continue to #2.
   If no, continue to #4.

2. Is the colorectal cancer RAS wild-type (mutation negative)?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**

3. Has the patient received previous treatment with an anti-EGFR therapy (e.g., Erbitux [cetuximab], Vectibix [panitumumab])?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) **AND** meet the following criterion?
   - The patient has received previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) (ICD-10 C22.0) **AND** meet the following criterion?
   - The patient has received previous treatment with Nexavar (sorafenib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #84 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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REGORAFENIB

GUIDELINE FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **REGORAFENIB (Stivarga)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic colorectal cancer (CRC: a type of digestive cancer that has spread to other parts of the body)
   2. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST: a type of digestive tumor that has spread from where it started to nearby tissue or lymph nodes, unable to remove by surgery, or has spread to other parts of the body)
   3. Hepatocellular carcinoma (HCC: a type of liver cancer)

B. If you have metastatic colorectal cancer, approval also requires:
   1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine
   2. You had previous treatment with an anti-VEGF therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept)
   3. If you have RAS wild-type (a type of unmutated gene) metastatic colorectal cancer, approval also requires you had previous treatment with an anti-EGFR therapy such as Erbitux (cetuximab), Vectibix (panitumumab)

C. If you have locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:
   1. You had previous treatment with Gleevec (imatinib) and Sutent (sunitinib)

D. If you have hepatocellular carcinoma, approval also requires:
   1. You had previous treatment with Nexavar (sorafenib)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stivarga.

REFERENCES

Stivarga [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc, December 2020.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RELACORILANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELACORILANT	LIFYORLI	51244		GPI-10 (2140536500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is platinum-resistant
   - Lifyorli will be used in combination with nab-paclitaxel
   - The patient has received one to three prior systemic treatment regimens, at least one of which included bevacizumab

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline named **RELACORILANT (Lifyorli)** requires the following rule(s) be met for approval:
   A. You have epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers)
   B. You are 18 years of age or older
   C. Your cancer is platinum-resistant (resistant to medications such as paclitaxel, docetaxel, cisplatin, carboplatin)
   D. Lifyorli will be used in combination with nab-paclitaxel
   E. You have received at least one to three prior systemic treatment regimens (treatment that targets the entire body), at least one of which included bevacizumab

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RELACORILANT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (ICD-10 Groups C56, C57.0, C48, C79.6) and meets **ALL** of the following criteria?
   - The patient has shown clinical benefit (radiographic response, stable disease)
   - The patient will continue nab-paclitaxel therapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **RELACORILANT (Lifyorli)** requires the following rule(s) be met for renewal:
   A. You have epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers)
   B. You have shown clinical benefit (radiographic [imaging] response, stable disease)
   C. You will continue nab-paclitaxel therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lifyorli.

REFERENCES

Lifyorli [Prescribing Information]. Redwood City, CA: Corcept Therapeutics Inc.; March 2026.

Created: 07/26
Effective: 08/01/26 DMC Approval: 07/14/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELUGOLIX	ORGOVYX	47035		GPI-10 (2140557000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced prostate cancer (ICD-10 C61) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for a total of 12 months as follows:**
   FOR INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month by HICL or GPI-10 with a quantity limit of #30 per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months by HICL or GPI-10 with a quantity limit of #1 per day (Please enter a start date of 3 WEEKS AFTER the START date of the first approval).**

   FOR SUBSEQUENT/MAINTENANCE REQUESTS:
   - **Approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RELUGOLIX (Orgovyx)** requires the following rule(s) be met for approval:
   A. You have advanced prostate cancer (a type of cancer that has spread to other parts of the body)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orgovyx.

REFERENCES

Orgovyx [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc.; October 2024.

Created: 02/21
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RELUGOLIX-ESTRADIOL-NORETHINDRONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RELUGOLIX/ ESTRADIOL/ NORETHINDRONE ACETATE	MYFEMBREE	47392		GPI-10 (2499350380)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Has the patient received a total of 24 months cumulative treatment with Myfembree?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) (ICD-10 Group D25) and the patient meets **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Oriahnn [elagolix/estradiol/norethindrone], Lupron Depot [leuprolide])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Is the request for the management of moderate to severe pain associated with endometriosis (ICD-10 Group N80 and R52) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is a premenopausal woman
   - Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN)
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day**.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
   2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

B. If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), approval also requires:
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. You will NOT use Myfembree concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Oriahnn [elagolix/estradiol/norethindrone], Lupron Depot [leuprolide])
   5. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. If the request is for management of moderate to severe pain associated with endometriosis, approval also requires:
   1. You are 18 years of age or older
   2. You are a premenopausal (before menopause) woman
   3. Therapy is prescribed by or in consultation with an obstetrician or gynecologist (OB/GYN: a type of women's health doctor)
   4. You will NOT use Myfembree concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])
   5. You have not received a total of 24 months cumulative (total) treatment with Myfembree

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

RENEWAL CRITERIA

1. Has the patient received a total of 24 months cumulative treatment with Myfembree?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) (ICD-10 D25.9) and the patient meets **ALL** of the following criteria?
   - The patient has had improvement of heavy menstrual bleeding
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Oriahnn [elagolix/estradiol/norethindrone], Lupron Depot [leuprolide])

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, continue to #3.

3. Is the request for the management of moderate to severe pain associated with endometriosis (ICD-10 Group N80 and R52) and the patient meets **ALL** of the following criteria?
   - The patient has had improvement in pain related to endometriosis
   - Myfembree will NOT be used concurrently with another GnRH-modulating agent (e.g., Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])

   If yes, **approve for 18 months (or up to 24 months cumulative lifetime treatment duration) by HICL or GPI-10 with a quantity limit of #1 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RELUGOLIX-ESTRADIOL-NORETHINDRONE (Myfembree)** requires the following rule(s) be met for renewal:
   A. The request is for ONE of the following:
      1. Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
      2. Management of moderate to severe pain associated with endometriosis (condition affecting the uterus)

   (Renewal denial text continued on next page)

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RELUGOLIX-ESTRADIOL-NORETHINDRONE

RENEWAL CRITERIA (CONTINUED)

B. If the request is for management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids), renewal also requires:
1. You had improvement of heavy menstrual bleeding on therapy
2. You will NOT use Myfembree concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Oriahnn [elagolix/estradiol/norethindrone], Lupron Depot [leuprolide])
3. You have not received a total of 24 months cumulative (total) treatment with Myfembree

C. If the request is for management of moderate to severe pain associated with endometriosis, renewal also requires:
1. You have had improvement in pain related to endometriosis (condition affecting the uterus) while on therapy
2. You will NOT use Myfembree concurrently (at the same time) with another gonadotropin-releasing hormone (GnRH)-modulating medication (such as Orilissa [elagolix], Lupron Depot [leuprolide], Synarel [nafarelin])
3. You have not received a total of 24 months cumulative (total) treatment with Myfembree

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myfembree.

REFERENCES

Myfembree [Prescribing Information]. Marlborough, MA: Sumitomo Pharma America, Inc.; August 2025.

Created: 06/21
Effective: 08/07/26 Client Approval: 08/26 DMC Approval: 08/04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REMIBRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REMIBRUTINIB	RHAPSIDO	50918		GPI-10 (9939376500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient still experiences hives or angioedema on most days of the week for at least 6 weeks
   - The patient had a trial of and is maintained on, OR has a contraindication to, 4-times the maximally labeled dose of a second generation H1 antihistamine (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
   - Rhapsido will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)
   - The patient had a trial of or contraindication to ONE preferred agent: Dupixent (dupilumab), Xolair (omalizumab)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REMIBRUTINIB (Rhapsido)** requires the following rule(s) be met for approval:
   A. You have chronic spontaneous urticaria (CSU) (also called chronic idiopathic urticaria [CIU]) [severe itching with unknown cause]
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   D. You still experience hives or angioedema (a type of swelling) on most days of the week for at least 6 weeks

   (Initial denial text continued on the next page)

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REMIBRUTINIB

INITIAL CRITERIA (CONTINUED)

E. You have tried and are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), 4-times the maximally labeled dose of a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine] dose of 40mg/day, Xyzal [levocetirizine] dose of 20mg/day, Claritin [loratadine] dose of 40mg/day, Clarinex [desloratadine] dose of 20mg/day, or Allegra [fexofenadine] dose of 720mg/day)
F. You will NOT use Rhapsido concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria) [severe itching with unknown cause]
G. You have tried or have a contraindication to (harmful for you to use) ONE preferred medication: Dupixent (dupilumab), Xolair (omalizumab)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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REMIBRUTINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) (ICD-10 L50.1, L50.8, L50.9) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an allergist, dermatologist, or immunologist
   - The patient is maintained on, OR has a contraindication to, a second generation H1 antihistamine (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
   - Rhapsido will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REMIBRUTINIB (Rhapsido)** requires the following rule(s) be met for renewal:
   A. You have chronic spontaneous urticaria (CSU) (also called chronic idiopathic urticaria [CIU]) [severe itching with unknown cause]
   B. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   C. You are maintained on (continue to use on a regular basis), OR you have a contraindication to (harmful for you to use), a second generation H1 antihistamine (type of allergy medication) (Zyrtec [cetirizine], Xyzal [levocetirizine], Claritin [loratadine], Clarinex [desloratadine], or Allegra [fexofenadine])
   D. You will NOT use Rhapsido concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic spontaneous urticaria (chronic idiopathic urticaria) [severe itching with unknown cause]

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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REMIBRUTINIB

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Rhapsido.

REFERENCES

Rhapsido [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2025.

Created: 10/25
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REPOTRECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REPOTRECTINIB	AUGTYRO	49312		GPI-10 (2153386500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has *ROS1*-positive tumors

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **40mg: #8 per day.**
   - **160mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have solid tumors and meet **ALL** of the following criteria?
   - The patient is 12 years of age and older
   - The tumors have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion
   - The tumors are locally advanced or metastatic, OR surgical resection is likely to result in severe morbidity
   - The patient has progressed following treatment OR has no satisfactory alternative therapy

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **40mg: #8 per day.**
   - **160mg: #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REPOTRECTINIB (Augtyro)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
      2. Solid tumors

   (Denial text continued on next page)

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REPOTRECTINIB

GUIDELINES FOR USE (CONTINUED)

B. If you have non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You have *ROS1*-positive (abnormal change in a type of gene) tumors

C. If you have solid tumors, approval also requires:
1. You are 12 years of age and older
2. Your tumors have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (abnormal change in a type of gene)
3. Yours tumors are locally advanced or metastatic (cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body), OR surgical resection (removal by surgery) is likely to result in severe morbidity (illness)
4. You have progressed following treatment OR have no satisfactory alternative (other) therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Augtyro.

REFERENCES
Augtyro [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/24
Created: 11/23
Client Approval: 06/24
P&T Approval: 10/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RESLIZUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RESLIZUMAB	CINQAIR	43211		GPI-10 (4460446000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (ICD-10 J82.83) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary medicine or allergy medicine
   - The patient has a blood eosinophil level of at least 150 cells/mcL within the past 12 months
   - Cinqair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Cinqair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko)

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months

     If yes, **approve for 4 months by HICL or GPI-10.**
     If no, continue to #3.

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RESLIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) reliever (e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 4 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for approval:
   A. You have severe asthma with an eosinophilic phenotype (a type of lung condition with inflammation)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (relating to lungs/breathing) medicine or allergy medicine
   D. You have a blood eosinophil (a type of white blood cell) level of at least 150 cells/mcL within the past 12 months
   E. Cinqair will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)

   (Initial denial text continued on next page)

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RESLIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

F. You will NOT use Cinqair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
G. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab), Tezspire (tezepelumab-ekko)
H. You meet ONE of the following:
    1. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months:
    2. You have experienced at least ONE serious asthma exacerbation requiring a hospitalization or an emergency room visit within the past 12 months
    3. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
        a. Daytime asthma symptoms more than twice per week
        b. Any night waking due to asthma
        c. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
        d. Any activity limitation due to asthma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RESLIZUMAB (NSA)

RENEWAL CRITERIA

1. Does the patient meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline, or an oral corticosteroid [e.g., prednisone])
   - Cinqair will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of eosinophilic phenotype asthma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RESLIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RESLIZUMAB (Cinqair)** requires the following rule(s) be met for renewal:

A. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), theophylline, or an oral corticosteroid (such as prednisone)
B. You will NOT use Cinqair concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of eosinophilic phenotype asthma
C. You have shown a clinical response as evidenced by ONE of the following:
    1. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline
    2. You have decreased your use of rescue medications (such as albuterol)
    3. You have an increase in the percent predicted FEV1 (a type of lung test) from pre-treatment baseline (before starting Cinqair)
    4. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cinqair.

REFERENCES

Cinqair [Prescribing Information]. West Chester, PA: Teva Respiratory, LLC; June 2020.

Created: 04/17
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RESMETIROM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RESMETIROM	REZDIFFRA	49451		GPI-10 (5260106000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-alcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH) (ICD-10 K75.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does NOT have cirrhosis
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or endocrinologist
   - The patient is enrolled in or has already completed a lifestyle intervention (e.g., dietary, exercise, psychology)
   - Rezdiffra will NOT be used concurrently with Wegovy for the treatment of NASH/MASH
   - The patient has a biopsy or non-invasive test (e.g., elastography, ELF testing) that was obtained in the past 12 months demonstrating liver fibrosis stage 2 or 3

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is Wegovy an excluded drug for this patient?
   (**NOTE:** Run a test claim for Wegovy to verify if it is an excluded benefit by the member's plan.)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Has the patient had a trial of or contraindication to Wegovy?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RESMETIROM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RESMETIROM (Rezdiffra)** requires the following rule(s) be met for approval:

A. You have non-alcoholic steatohepatitis (NASH: a type of liver disease)/metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)
B. You are 18 years of age or older
C. You do NOT have cirrhosis (liver damage and scarring)
D. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (doctor who treats digestive conditions), or endocrinologist (a type of hormone doctor)
E. You are enrolled in or have already completed a lifestyle intervention (such as dietary, exercise, psychology)
F. You will NOT use Rezdiffra concurrently (at the same time) with Wegovy for the treatment of non-alcoholic steatohepatitis (NASH: a type of liver disease)/metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)
G. You have had a biopsy (removal of cells or tissue from the body for examination) or non- invasive test (such as elastography [type of imaging test], Enhanced Liver Fibrosis [ELF] testing [a type of blood test]) in the past 12 months which shows you have liver fibrosis stage 2 or 3 (scoring system to measure liver damage)
H. If Wegovy is covered by your plan, approval also requires:
    1. You have tried or have a contraindication to (harmful for you to use) Wegovy

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RESMETIROM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of non-alcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH) (ICD-10 K75.81) and meet **ALL** of the following criteria?
   - The patient has shown disease stability or an improvement from baseline
   - Rezdiffra will NOT be used concurrently with Wegovy for the treatment of NASH/MASH
   - The patient had a biopsy or non-invasive test (e.g., elastography, ELF testing) demonstrating liver fibrosis stage 2 or 3

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RESMETIROM (Rezdiffra)** requires the following rule(s) be met for renewal:
   A. You have non-alcoholic steatohepatitis (NASH: a type of liver disease)/metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)
   B. Your disease is stable or has improved from baseline (before treatment with Rezdiffra)
   C. You will NOT use Rezdiffra concurrently (at the same time) with Wegovy for the treatment of non-alcoholic steatohepatitis (NASH: a type of liver disease)/metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)
   D. You have had a biopsy (removal of cells or tissue from the body for examination) or non- invasive test (such as elastography [type of imaging test], Enhanced Liver Fibrosis [ELF] testing [a type of blood test]) which shows you have liver fibrosis stage 2 or 3 (scoring system to measure liver damage)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezdiffra.

REFERENCES

Rezdiffra [Prescribing Information]. West Conshohocken, PA: Madrigal Pharmaceuticals; December 2025.

Created: 03/24
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RETIFANLIMAB-DLWR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RETIFANLIMAB-DLWR	ZYNYZ	48795		GPI-10 (2135796020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) (ICD-10 C7B.1; Group C4A) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.715mL per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) (ICD-10 C44.520) **AND** meet the following criterion?
   - The patient is 18 years of age or

   older If yes, continue to #3.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - Zynyz will be used in combination with carboplatin and paclitaxel AND the patient's cancer is inoperable
   - Zynyz will be used as a single agent AND the patient has experienced disease progression on or is intolerant to platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.953mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RETIFANLIMAB-DLWR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RETIFANLIMAB-DLWR (Zynyz)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic or recurrent locally advanced Merkel cell carcinoma (MCC: a type of skin cancer that has spread to other parts of the body or has returned and spread from where it started to nearby tissue or lymph nodes)
   2. Locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC: a type of cancer of the anal canal that has returned from where it started or has spread to other parts of the body)

B. If you have metastatic or recurrent locally advanced Merkel cell carcinoma, approval also requires:
   1. You are 18 years of age or older

C. If you have locally recurrent or metastatic squamous cell carcinoma of the anal canal, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. Zynyz will be used in combination with carboplatin and paclitaxel AND your cancer is inoperable (not able to operate on)
      b. Zynyz will be used as a single agent (used alone) AND your disease has progressed (worsened) while on platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin) or you are intolerant (side effects) to platinum-based chemotherapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zynyz.

REFERENCES

Zynyz [Prescribing Information]. Wilmington, DE: Incyte Corporation; March 2026.

Created: 04/23
Effective: 04/29/26 Client Approval: 04/26 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REVUMENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REVUMENIB CITRATE	REVUFORJ	50008		GPI-10 (2148007020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute leukemia (ICD-10 C91.00, C91.02, C92.00, C92.02, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C95.00, C95.02) **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a lysine methyltransferase 2A gene (KMT2A) translocation, as determined by an FDA-authorized test
   - The patient has a susceptible nucleophosmin 1 (NPM1) mutation AND has no satisfactory alternative treatment options

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **25mg: #8 per day.**
   - **110mg: #4 per day.**
   - **160mg: #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REVUMENIB (Revuforj)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute leukemia (a type of blood cancer that has returned or did not respond to treatment)
   B. You are 1 year of age or older
   C. You meet ONE of the following:
      1. You have a lysine methyltransferase 2A gene (KMT2A) translocation (a type of gene abnormality), as determined by a Food and Drug Administration (FDA)-authorized test
      2. You have a susceptible nucleophosmin 1 (NPM1) mutation (an abnormal change in gene) AND you have no satisfactory alternative treatment options

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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REVUMENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revuforj.

REFERENCES

Revuforj [Prescribing Information]. Waltham, MA: Syndax Pharmaceuticals, Inc.; October 2025.

Created: 11/24
Effective: 12/01/25 Client Approval: 11/25 P&T Approval: 01/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

REZAFUNGIN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
REZAFUNGIN ACETATE	REZZAYO	48846		GPI-10 (1150007010)	

GUIDELINES FOR USE

1. Is the request for the treatment of candidemia or invasive candidiasis (ICD-10 Group B37 except B37.81 and Group B37.3) and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has limited or no alternative treatment options

   If yes, **approve for 4 weeks by HICL or GPI-10 with a quantity limit of #5 per 28 days (do not enter as MDD).**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **REZAFUNGIN (Rezzayo)** requires the following rule(s) be met for approval:
   A. The request is for the treatment of candidemia (a type of fungal infection) or invasive candidiasis (a type of fungal infection)
   B. You are 12 years of age or older
   C. You have limited or no alternative treatment options

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rezzayo.

REFERENCES

Rezzayo [Prescribing Information]. Lincolnshire, IL: Melinta Therapeutics LLC.; July 2026.

Created: 07/23
Effective: 07/31/26 Client Approval: 07/26 DMC Approval: 08/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIBOCICLIB SUCCINATE	KISQALI	44151		GPI-10 (2153107050)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) **AND** meet the following criterion?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient in stage II or III early cancer and the patient meets **ALL** of the following criteria?
   - Kisqali will be used in combination with an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole) for adjuvant treatment
   - The patient is at high risk of recurrence

   If yes, **approve all daily dosage strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **200mg daily dose: #21 per 28 days.**
   - **400mg daily dose: #42 per 28 days.**

   If no, continue to #3.

3. Is the patient's cancer advanced or metastatic and the patient meets **ONE** of the following criteria?
   - Kisqali will be used in combination with an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole) as initial endocrine-based therapy
   - Kisqali will be used in combination with fulvestrant (Faslodex), as initial endocrine-based therapy or following disease progression on endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

   If yes, **approve all daily dosage strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **200mg daily dose: #21 per 28 days.**
   - **400mg daily dose: #42 per 28 days.**
   - **600mg daily dose: #63 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RIBOCICLIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **RIBOCICLIB (Kisqali)** requires the following rule(s) be met for approval:

A. You have breast cancer
B. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
C. You meet ONE of the following:
    1. You have stage II or III early breast cancer (initial stage of cancer); you will use Kisqali in combination with an aromatase inhibitor (such as anastrozole, exemestane, letrozole) for adjuvant (add-on) treatment; AND you are at high risk of recurrence (disease returning)
    2. You have advanced or metastatic breast cancer (cancer that has progressed or has spread to other parts of the body), and you meet ONE of the following:
        a. You will use Kisqali in combination with an aromatase inhibitor (such as anastrozole, exemestane, letrozole) as initial endocrine (hormone)-based therapy
        b. You will use Kisqali in combination with fulvestrant (Faslodex), as initial endocrine (hormone)-based therapy or following disease progression (your condition worsened) on endocrine (hormone) therapy (such as anastrozole, letrozole, tamoxifen)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali.

REFERENCES

Kisqali [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2024.

Created: 05/17
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB-LETROZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIBOCICLIB SUCCINATE/ LETROZOLE	KISQALI FEMARA CO-PACK	44246		GPI-10 (2199000260)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of stage II or III early breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   - Kisqali Femara Co-Pack will be used for adjuvant treatment
   - The patient is at high risk of recurrence

   If yes, **approve all daily dosage strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **200mg-2.5mg daily dose: #49 per 28 days.**
   - **400mg-2.5mg daily dose: #70 per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Groups C50, C79.81) and meet **ALL** of the following criteria?
   - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
   - Kisqali Femara Co-Pack will be used as initial endocrine-based therapy

   If yes, **approve all daily dosage strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **200mg-2.5mg daily dose: #49 per 28 days.**
   - **400mg-2.5mg daily dose: #70 per 28 days.**
   - **600mg-2.5mg daily dose: #91 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RIBOCICLIB-LETROZOLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **RIBOCICLIB-LETROZOLE (Kisqali Femara Co-Pack)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Stage II or III early breast cancer (initial stage of breast cancer)
   2. Advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of the body)

B. If you have stage II or III early breast cancer, approval also requires:
   1. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   2. Kisqali Femara Co-Pack will be used for adjuvant (add-on) treatment
   3. You are at high risk of recurrence (disease returning)

C. If you have advanced or metastatic breast cancer, approval also requires:
   1. Your cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   2. Kisqali Femara Co-Pack will be used as initial endocrine (hormone)-based therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali Femara Co-Pack.

REFERENCES

Kisqali Femara Co-Pack [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/21/24
Created: 03/23
Client Approval: 10/24
P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIFAXIMIN 200MG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIFAXIMIN	XIFAXAN		93749	GPI-14 (16000049000320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of travelers' diarrhea (TD) (ICD-10 A09) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a trial of or contraindication to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

   If yes, **approve for 3 days by GPID or GPI-14 for 1 fill of #9.**
   If no, continue to #2.

2. Does the patient have a diagnosis of overt hepatic encephalopathy (HE) (ICD-10 K76.82) **AND** meet the following criterion?
   - Xifaxan will be used in combination with lactulose

   If yes, **approve for 10 days by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of *Clostridium difficile* infection (CDI) (ICD-10 Group A04.7) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an infectious disease specialist
   - The patient had at least one previous occurrence of Clostridium difficile infection
   - The patient has been treated with vancomycin for the current *Clostridium difficile* infection

   If yes, **approve for 20 days by GPID or GPI-14 with a quantity limit of #6 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RIFAXIMIN 200MG

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIFAXIMIN 200MG (Xifaxan)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Travelers' diarrhea
   2. Overt hepatic encephalopathy (HE: a type of brain condition caused by liver damage)
   3. *Clostridium difficile* infection (a type of bacterial infection)

B. If you have travelers' diarrhea, approval also requires:
   1. You are 12 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin

C. If you have overt hepatic encephalopathy, approval also requires:
   1. Xifaxan will be used in combination with lactulose

D. If you have *Clostridium difficile* infection, approval also requires:
   1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
   2. You had at least one previous occurrence of *Clostridium difficile* infection
   3. You have been treated with vancomycin for the current *Clostridium difficile* infection

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information for Xifaxan.

REFERENCES

Xifaxan [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals; October 2023.

Created: 02/05
Effective: 12/01/25 Client Approval: 11/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILONACEPT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RILONACEPT	ARCALYST	35438		GPI-10 (6645006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) (ICD-10 M04.2) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has genetic testing for gain-of-function mutations in the *NLRP3* gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein [SAA] or S100 proteins)
   - The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   - Arcalyst will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CAPS

   If yes, **enter TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL:**
     - **Approve for 1 month with a quantity limit of #5 per 28 days.**
   - **SECOND APPROVAL:**
     - **Approve for lifetime with a quantity limit of #4 per 28 days (enter a start date of 3 days BEFORE the END of the first approval).**

   If no, continue to #2.

2. Does the patient have a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) (ICD-10 M04.8) and meet **ALL** of the following criteria?
   - The patient has genetic testing for gain-of-function mutations in the *IL1RN* gene OR has inflammatory markers (i.e., elevated CRP, ESR)
   - The patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis)
   - Arcalyst will NOT be used concurrently with another systemic biologic (e.g., Kineret [anakinra]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DIRA

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, continue to #3.

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RILONACEPT

INITIAL CRITERIA (CONTINUED)

3. Is the request for the treatment or reduction in risk of recurrent pericarditis (RP) (ICD-10 I31.9) and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had an episode of acute pericarditis
   - The patient has been symptom-free for an interval of 4 to 6 weeks
   - The patient has TWO of the following: chest pain consistent with pericarditis, pericardial friction rub, ECG showing diffuse ST-segment elevation or PR-segment depression, and new or worsening pericardial effusion
   - The patient had a trial of or contraindication to the following clinical standard of care agents: two NSAIDs (e.g., ibuprofen, indomethacin) AND colchicine
   - Arcalyst will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of recurrent pericarditis

   If yes, **enter TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL:**
     - **Approve for 1 month with a quantity limit of #5 per 28 days.**
   - **SECOND APPROVAL:**
     - **Approve for 11 months with a quantity limit of #4 per 28 days (enter a start date of 3 days BEFORE the END of the first approval).**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILONACEPT (Arcalyst)** requires the following rule(s) be met for approval:

   A. You meet ONE of the following:
      1. You have Cryopyrin-Associated Periodic Syndromes (CAPS: a type of immune disorder) including, Familial Cold Autoinflammatory Syndrome (FCAS: a type of immune disorder) or Muckle-Wells Syndrome (MWS: a type of gene disorder)
      2. You have Deficiency of Interleukin-1 Receptor Antagonist (DIRA: a type of immune system disorder)
      3. Arcalyst will be used for the treatment or reduction in risk of recurrent pericarditis (RP: a type of heart condition that returns)

   (Initial denial text continued on next page)

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RILONACEPT

INITIAL CRITERIA (CONTINUED)

B. If you have Cryopyrin-Associated Periodic Syndromes including Familial Cold Autoinflammatory Syndrome or Muckle-Wells Syndrome, approval also requires:

1. You are 12 years of age or older
2. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
3. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
4. You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Cryopyrin-Associated Periodic Syndromes (a type of immune system disorder)

C. If you have Deficiency of Interleukin-1 Receptor Antagonist, approval also requires:

1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: a measure of how much inflammation is in the body], erythrocyte sedimentation rate [ESR: a measure of how much inflammation is in the body])
2. You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: fungal infection of toenail)
3. You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic (such as Kineret [anakinra]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (a type of immune system disorder)

(Initial denial text continued on next page)

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RILONACEPT

INITIAL CRITERIA (CONTINUED)

D. If the request is for the treatment or reduction in risk of recurrent pericarditis, approval also requires:

1. You are 12 years of age or older
2. You had an episode of acute pericarditis (a type of short-term heart condition)
3. You have been symptom-free for 4 to 6 weeks
4. You have TWO of the following: chest pain consistent with pericarditis, pericardial friction rub (a type of heart condition), electrocardiogram (ECG: a type of lab test) showing diffuse ST-segment elevation or PR-segment depression (an abnormal heart test), and new or worsening pericardial effusion (a type of heart condition)
5. You have tried or have a contraindication to (harmful for you to use) the following clinical standard of care medications: two NSAIDS (non-steroidal anti-inflammatory drugs such as ibuprofen, indomethacin) AND colchicine
6. You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of recurrent pericarditis (a type of heart condition that returns)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RILONACEPT

RENEWAL CRITERIA

NOTE: For the diagnoses of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), or Deficiency of Interleukin-1 Receptor Antagonist (DIRA), please refer to the Initial Criteria section.

1. Is the request for the treatment or reduction in risk of recurrent pericarditis (RP) (ICD-10 I31.9) and the patient meets **ALL** of the following criteria?
   - The patient has had a reduction of pericarditis recurrence or improvement in symptoms
   - Arcalyst will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of recurrent pericarditis

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per 28 days**. If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILONACEPT (Arcalyst)** requires the following rule(s) be met for renewal:
   A. Arcalyst will be used for the treatment or reduction in risk of recurrent pericarditis (RP: a type of heart condition that returns)
   B. You have had a reduction in pericarditis recurrence (a type of heart condition that has come back less often) or improvement in symptoms
   C. You will NOT use Arcalyst concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of recurrent pericarditis (a type of heart condition that returns)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arcalyst.

REFERENCES

Arcalyst [Prescribing Information]. London, UK: Kiniksa Pharmaceuticals; May 2021.

Created: 08/23
Effective: 04/01/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILUZOLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RILUZOLE	EXSERVAN, TIGLUTIK	10247		GPI-10 (7450307000)	FORM ≠ TABLET

GUIDELINES FOR USE

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) (ICD-10 G12.21) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of the preferred agent: riluzole tablets
   - The patient is unable to take riluzole tablet formulation

   If yes, **approve all formulations for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Exservan: #2 per day.**
   - **Tiglutik: #20mL per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILUZOLE (Exservan, Tiglutik)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You are 18 years of age or older
   C. You have tried the preferred medication: riluzole tablets
   D. You are unable to take riluzole tablet formulation

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exservan or Tiglutik.

REFERENCES

Exservan. [Prescribing Information]. Warren, NJ: Aquestive Therapeutics; May 2020.
Tiglutik. [Prescribing Information]. Paoli, PA: EDW Pharma, Inc.; September 2025.

Created: 11/18
Effective: 03/04/26 Client Approval: 03/26 P&T Approval: 01/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILZABRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RILZABRUTINIB	WAYRILZ	50857		GPI-10 (8575205000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of persistent or chronic immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to a corticosteroid or IV immunoglobulin, OR had an insufficient response to a splenectomy
   - The patient has a platelet count of less than 30 x 10^9/L, OR has a platelet count of less than 50 x 10^9/L and had a prior bleeding event
   - The patient had a trial of or contraindication to a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib]) OR a thrombopoietin receptor agonist (e.g., Doptelet [avatrombopag], Promacta [eltrombopag])
   - Wayrilz will NOT be used concurrently with a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib])

   If yes, **approve for 3 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILZABRUTINIB (Wayrilz)** requires the following rule(s) be met for approval:
   A. You have persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) a corticosteroid or intravenous (injection into the vein) immunoglobulin, OR you did not have a good enough response to a splenectomy (spleen removal)
   D. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L, OR you have a platelet count of less than 50 x 10^9/L and had a prior bleeding event
   E. You have tried or have a contraindication to (harmful for you to use) a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib]) OR a thrombopoietin receptor agonist (such as Doptelet [avatrombopag], Promacta [eltrombopag])
   F. You will NOT use Wayrilz concurrently (at the same time) with a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RILZABRUTINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of persistent or chronic immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as having an improvement in platelet counts from baseline OR a reduction in bleeding events
   - Wayrilz will NOT be used concurrently with a spleen tyrosine kinase (SYK) inhibitor (e.g., Tavalisse [fostamatinib])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILZABRUTINIB (Wayrilz)** requires the following rule(s) be met for renewal:
   A. You have persistent or chronic immune thrombocytopenia (ITP: a type of blood disorder)
   B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline OR a decrease in bleeding events
   C. You will NOT use Wayrilz concurrently (at the same time) with a spleen tyrosine kinase (SYK) inhibitor (such as Tavalisse [fostamatinib])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wayrilz.

REFERENCES

Wayrilz [Prescribing Information]. Cambridge, MA: Genzyme Corporation; August 2025.

Created: 09/25
Effective: 10/01/25 Client Approval: 09/25 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIMABOTULINUM TOXIN B (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIMABOTULINUM TOXIN B	MYOBLOC	21869		GPI-10 (7440002010)	

GUIDELINES FOR USE

1. Is the request for a cosmetic indication (e.g., wrinkles - glabellar lines, lateral canthal lines, forehead lines)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2,500u/0.5mL: #1mL every 3 months.**
   - **5,000u/1mL: #1mL every 3 months.**
   - **10,000u/2mL: #2mL every 3 months.**

   If no, continue to #3.

3. Does the patient have a diagnosis of chronic sialorrhea (drooling or excessive salivation) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2,500u/0.5mL: #1mL every 3 months.**
   - **5,000u/1mL: #1mL every 3 months.**
   - **10,000u/2mL: #2mL every 3 months.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline

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RIMABOTULINUM TOXIN B (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIMABOTULINUM TOXIN B (Myobloc)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Cervical dystonia (a type of muscle condition)
   2. Chronic sialorrhea (drooling or excessive salivation)

B. You are 18 years of age or older

NOTE: This medication will not be approved for a cosmetic indication (for example wrinkles - glabellar lines, lateral canthal lines, forehead lines).

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Myobloc.

REFERENCES

Myobloc [Prescribing Information] South San Francisco, CA: Solstice Neurosciences, Inc.; August 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIMEGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIMEGEPANT SULFATE	NURTEC ODT	46383		GPI-10 (6770106070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute treatment of migraines
   - The patient had a trial of or contraindication to the clinical standard of care agent: ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, continue to #2.

2. Is the request for the preventive treatment of episodic migraines and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIMEGEPANT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. Acute (quick onset) treatment of migraines (a type of headache)
   2. Preventive treatment of episodic migraines (a type of headache)

B. If the request is for the acute treatment of migraines, approval also requires:
   1. You are 18 years of age or older
   2. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Zavzpret [zavegepant], Ubrelvy [ubrogepant]) for the acute (quick onset) treatment of migraines (a type of headache)
   3. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

C. If the request is for the preventive treatment of episodic migraines (0-14 headache days per month), approval also requires:
   1. You are 18 years of age or older
   2. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine (a type of headache) prevention

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RIMEGEPANT

RENEWAL CRITERIA

NOTE: For the diagnosis of acute treatment of migraines, please refer to the Initial Criteria section.

1. Is the request for the preventive treatment of episodic migraines **AND** the patient meets the following criterion?
   - Nurtec ODT will NOT be used concurrently with other CGRP inhibitors (e.g., Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine prevention

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month
   - The patient has experienced a reduction in migraine severity
   - The patient has experienced a reduction in migraine duration

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:
   A. The request is the preventive treatment of episodic migraines (a type of headache, 0-14 headache days per month):
   B. You will NOT use Nurtec ODT concurrently (at the same time) with other calcitonin gene-related peptide (CGRP) inhibitors (such as Ajovy [fremanezumab-vfrm], Aimovig [erenumab-aooe], Emgality [galcanezumab-gnlm], Vyepti [eptinezumab-jjmr], Qulipta [atogepant]) for migraine (a type of headache) prevention
   C. You meet ONE of the following:
      1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month
      2. You have experienced a reduction in migraine severity
      3. You have experienced a reduction in migraine duration

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RIMEGEPANT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nurtec ODT.

REFERENCES

Nurtec ODT [Prescribing Information]. New York, NY: Pfizer Inc.; March 2026.

Created: 03/20
Effective: 04/01/26 Client Approval: 03/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIOCIGUAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIOCIGUAT	ADEMPAS	40644		GPI-10 (4013405000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - Adempas will NOT be used concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) (ICD-10 I27.24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient has persistent or recurrent disease after surgical treatment OR is not a candidate for surgery OR has inoperable CTEPH
   - The patient has NYHA-WHO Functional Class II to IV symptoms
   - Adempas will NOT be used concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RIOCIGUAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   2. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization [WHO] Group 4)

B. If you have pulmonary arterial hypertension, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   3. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   4. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

C. If you have chronic thromboembolic pulmonary hypertension, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   3. You have persistent or recurrent disease after surgical treatment (condition continues to exist or returns after surgery) OR you are not a candidate for surgery OR you have inoperable (not able to operate on) chronic thromboembolic pulmonary hypertension
   4. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   5. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIOCIGUAT

RENEWAL CRITERIA

1. Does the patient have ONE of the following diagnoses?
   - Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) (ICD-10 I27.24)
   - Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Will Adempas be taken concurrently with nitrates or nitric oxide donors (e.g., amyl nitrate), phosphodiesterase inhibitors (e.g., Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (e.g., dipyridamole, theophylline)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH: a type of heart and lung condition) (World Health Organization [WHO] Group 4)
      2. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You will NOT use Adempas concurrently (at the same time) with nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as Viagra [sildenafil], Cialis [tadalafil], Levitra [vardenafil]), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RIOCIGUAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adempas.

REFERENCES

Adempas [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 11/13
Client Approval: 06/24
P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RIPRETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIPRETINIB	QINLOCK	46544		GPI-10 (2153305300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received prior treatment with at least THREE kinase inhibitors (e.g., Sutent [sunitinib], Ayvakit [avapritinib], Stivarga [regorafenib]), including Gleevec (imatinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RIPRETINIB (Qinlock)** requires the following rule(s) be met for approval:
   A. You have advanced gastrointestinal stromal tumor (GIST: a type of digestive system cancer)
   B. You are 18 years of age or older
   C. You have received prior treatment with at least THREE kinase inhibitors (such as Sutent [sunitinib], Ayvakit [avapritinib], Stivarga [regorafenib]), including Gleevec (imatinib)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qinlock.

REFERENCES

Qinlock [Prescribing Information]. Waltham, MA: Deciphera Pharmaceuticals, LLC; November 2024.

Created: 07/20
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISANKIZUMAB-RZAA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RISANKIZUMAB-RZAA	SKYRIZI	45699		GPI-10 (9025057070, 5250406070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Skyrizi
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**

   If no, continue to #5.

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
   - **180mg/1.2mL: #1.2 mL per 56 days**
   - **360mg/2.4mL: #2.4 mL per 56 days**

   (Please enter a 3 month approval by GPID or GPI-14 for the 600mg/10mL strength with a quantity limit of #10 mL per 28 days.)

   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, approve for 6 months by GPID or GPI-14 for all strengths as follows:
   - **180 mg/1.2 mL: #1.2 mL per 56 days**
   - **360 mg/2.4 mL: #2.4 mL per 56 days**

   (Please enter a 3 month approval by GPID or GPI-14 for the 600mg/10mL strength with a quantity limit of #20 mL per 28 days.)

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe plaque psoriasis, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of one clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Skyrizi
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp

C. If you have psoriatic arthritis, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

(Initial denial text continued on next page)

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RISANKIZUMAB-RZAA

INITIAL CRITERIA (CONTINUED)

D. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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RISANKIZUMAB-RZAA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **180mg/1.2mL: #1.2mL per 56 days.**
   - **360mg/2.4mL: #2.4mL per 56 days.**

   If no, continue to #4.

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RISANKIZUMAB-RZAA

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Skyrizi will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following strengths:**
   - **180mg/1.2mL: #1.2mL per 56 days.**
   - **360mg/2.4mL: #2.4mL per 56 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
      2. Psoriatic arthritis (PsA: a type of skin and joint condition)
      3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
      4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

   B. If you have moderate to severe plaque psoriasis, renewal also requires:
      1. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
      2. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis

   C. If you have psoriatic arthritis, renewal also requires:
      1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
      2. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease

E. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use Skyrizi concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis

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RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyrizi.

REFERENCES
Skyrizi [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; June 2026.

Created: 05/19
Effective: 07/15/26 Client Approval: 07/26 DMC Approval: 07/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISDIPLAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RISDIPLAM	EVRYSDI	46765		GPI-10 (7470656000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) (ICD-10 G12.9) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
- The diagnosis is confirmed by gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1) gene (e.g., homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [i.e., deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient pre-symptomatic **AND** meets the following criterion?
- The patient has up to (i.e., no more than) THREE copies of the survival motor neuron 2 (SMN2) gene based on newborn screening

If yes, **approve all formulations for 12 months by GPID or GPI-14 with the following quantity limits:**
- **5 mg: #1 per day.**
- **0.75 mg/mL: #8mL per day.**

If no, continue to #3.

3. Is the patient symptomatic and meets **ALL** of the following criteria?
- The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
- The patient had a baseline motor function assessment by a neuromuscular specialist or SMA specialist
- If the patient received prior gene therapy, the patient had a less than expected clinical benefit with gene therapy

If yes, **approve all formulations for 12 months by GPID or GPI-14 with the following quantity limits:**
- **5 mg: #1 per day.**
- **0.75 mg/mL: #8mL per day.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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RISDIPLAM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for approval:

A. You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
B. Therapy is prescribed by or in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
C. Your diagnosis is confirmed by a gene mutation (abnormal change) analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
D. If you are pre-symptomatic (symptoms have not yet appeared), approval also requires:
    1. You have up to (no more than) THREE copies of the survival motor neuron 2 (SMN2: type of protein) gene based on a screening that was done when you were a newborn
E. If you are symptomatic (symptoms have appeared), approval also requires:
    1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
    2. You had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
    3. If you have received prior gene therapy, you experienced a less than expected clinical benefit with gene therapy

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RISDIPLAM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of spinal muscular atrophy (SMA) (ICD-10 G12.9) and meet **ONE** of the following criteria?
- The patient has improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline (e.g., HINE, HFMSE, CHOP-INTEND)
- The patient has improved, maintained, or demonstrated a less than expected decline in other muscle function (e.g., pulmonary)

If yes, **approve all formulations for 12 months by GPID or GPI-14 with the following quantity limits:**
- **5 mg: #1 per day.**
- **0.75 mg/mL: #8mL per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for renewal:
A. You have spinal muscular atrophy (SMA: a type of nerve and muscle movement disorder)
B. You meet ONE of the following:
   1. You have improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE), and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
   2. You have improved, maintained, or demonstrated a less than expected decline in other muscle function (such as pulmonary [lung/breathing] function)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Evrysdi.

REFERENCES
Evrysdi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; February 2025.

Created: 08/20
Effective: 03/03/25 Client Approval: 02/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITLECITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITLECITINIB TOSYLATE	LITFULO	49026		GPI-10 (9073106010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe alopecia areata (ICD-10 Group L63) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has experienced at least 50 percent scalp hair loss, as measured by the Severity of Alopecia Tool (SALT), for at least 6 months
   - Litfulo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Olumiant (baricitinib)], PDE-4 inhibitor) for the treatment of alopecia areata

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITLECITINIB (Litfulo)** requires the following rule(s) be met for approval:
   A. You have severe alopecia areata (a type of hair loss)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   D. You have experienced at least 50 percent scalp hair loss, as measured by the Severity of Alopecia Tool (SALT: a type of disease evaluation tool), for at least 6 months
   E. You will NOT use Litfulo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Olumiant (baricitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITLECITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe alopecia areata (ICD-10 Group L63) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on therapy (e.g., scalp hair coverage)
   - Litfulo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Olumiant (baricitinib)], PDE-4 inhibitor) for the treatment of alopecia areata

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RITLECITINIB (Litfulo)** requires the following rule(s) be met for renewal:
   A. You have severe alopecia areata (a type of hair loss)
   B. You have shown improvement while on therapy (such as scalp hair coverage)
   C. You will NOT use Litfulo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Olumiant (baricitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of alopecia areata

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Litfulo.

REFERENCES

Litfulo [Prescribing Information]. New York, NY: Pfizer Inc.; June 2023.

Created: 07/23
Effective: 03/17/25 Client Approval: 03/25 P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB	RITUXAN	16848		GPI-10 (2135186000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is currently using or has a contraindication to methotrexate
   - Rituxan will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 for #2 fills.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 for up to #8 fills.**
     If no, continue to #4.

4. Does the patient have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), Burkitt lymphoma (BL) (ICD-10 Group C83.7), Burkitt-like lymphoma (BLL) (ICD-10 Group C83.7) or mature B-cell acute leukemia (B-AL) (ICD-10 Group C91.A) and meet **ALL** of the following criteria?
   - The patient is 6 months to 17 years of age
   - Therapy is prescribed by or in consultation with an oncologist
   - Rituxan will be used in combination with chemotherapy (e.g., CVP [cyclophosphamide-vincristine- prednisolone])
   - Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL, BL, BLL, or B-AL
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 for up to #6 fills.**
     If no, continue to #5.

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Rituxan will be used in combination with chemotherapy (e.g., fludarabine, cyclophosphamide)
   - Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by HICL or GPI-10 for up to #6 fills.**
     If no, continue to #6.

6. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Rituxan will be used in combination with glucocorticoids (e.g., methylprednisolone, prednisone)
   - Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 for #4 fills.**
     If no, continue to #7.

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Rituxan will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
     If no, continue to #8.

8. Is the request for an FDA-approved indication **AND** Rituxan will be used in combination with another chemotherapy agent(s)?
   [**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with Rituxan. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
   3. Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt- like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
   4. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   5. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
   6. Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
   7. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
   8. Rituxan will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
4. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. If you have non-Hodgkin's lymphoma, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
3. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin’s lymphoma (a type of blood cancer)
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

D. If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:
1. You are 6 months to 17 years of age
2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
3. Rituxan will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
4. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia (types of blood cancer)
5. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

E. If you have chronic lymphocytic leukemia, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
3. Rituxan will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
4. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia (a type of blood cancer)
5. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

F. If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:
1. You are 2 years of age or older
2. Rituxan will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
3. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis (conditions that affect the blood vessels)
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

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RITUXIMAB

INITIAL CRITERIA (CONTINUED)

G. If you have moderate to severe pemphigus vulgaris, approval also requires:
1. You are 18 years of age or older
2. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris (a type of skin condition)
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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RITUXIMAB

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - Rituxan will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RITUXIMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB (Rituxan)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count from baseline while on therapy
C. You will NOT use Rituxan concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
D. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
        a. Enbrel (etanercept)
        b. Adalimumab-ryvk/adalimumab-aaty
        c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
        d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rituxan.

REFERENCES

Rituxan [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2021.

Created: 01/09
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB-ABBS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB-ABBS	TRUXIMA	45522		GPI-10 (2135186010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #8 fills.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Truxima will be used in combination with chemotherapy (e.g., fludarabine, cyclophosphamide)
   - Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve for 6 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is currently using or has a contraindication to methotrexate
   - Truxima will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #4.
   If no, continue to #5.

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RITUXIMAB-ABBS

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by HICL or GPI-10 for #2 fills.**
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Truxima will be used in combination with glucocorticoids (e.g., methylprednisolone, prednisone)
   - Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA

     If yes, **approve for 12 months by HICL or GPI-10 for #4 fills.**
     If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV

     If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
     If no, continue to #7.

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RITUXIMAB-ABBS

INITIAL CRITERIA (CONTINUED)

7. Does the patient have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), Burkitt lymphoma (BL) (ICD-10 Group C83.7), Burkitt-like lymphoma (BLL) (ICD-10 Group C83.7) or mature B-cell acute leukemia (B-AL) (ICD-10 Group C91.A) and meet **ALL** of the following criteria?
   - The patient is 6 months to 17 years of age
   - Therapy is prescribed by or in consultation with an oncologist
   - Truxima will be used in combination with chemotherapy (e.g., CVP [cyclophosphamide-vincristine-prednisolone])
   - Truxima will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL, BL, BLL, or B-AL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #8.

8. Is the request for an FDA-approved indication **AND** Truxima will be used in combination with another chemotherapy agent(s)?
   [**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with Truxima. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB-ABBS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
   2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   3. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   4. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
   5. Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
   6. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
   7. Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt- like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
   8. Truxima will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

B. If you have non-Hodgkin's lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin’s lymphoma (a type of blood cancer)

C. If you have chronic lymphocytic leukemia, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. Truxima will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
   4. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia (a type of blood cancer)

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RITUXIMAB-ABBS

INITIAL CRITERIA (CONTINUED)

D. If you have moderate to severe rheumatoid arthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
4. You will NOT use Truxima concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
5. You have tried at least 3 months of or have a contraindication to clinical standard of care medication: a ONE conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RITUXIMAB-ABBS

INITIAL CRITERIA (CONTINUED)

E. If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:
1. You are 2 years of age or older
2. Truxima will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
3. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis (conditions that affect the blood vessels)

F. If you have moderate to severe pemphigus vulgaris, approval also requires:
1. You are 18 years of age or older
2. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris (a type of skin condition)

G. If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:
1. You are 6 months to 17 years of age
2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
3. Truxima will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
4. You will NOT use Truxima concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia (types of blood cancer)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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RITUXIMAB-ABBS

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - Truxima will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RITUXIMAB-ABBS

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **RITUXIMAB-ABBS (Truxima)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
C. You will NOT use Truxima concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
D. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
        a. Enbrel (etanercept)
        b. Adalimumab-ryvk/adalimumab-aaty
        c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
        d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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RITUXIMAB-ABBS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Truxima and Rituxan.

REFERENCES

Truxima [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; June 2025.
Rituxan [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2021.

Created: 11/19
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB-ARRX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB-ARRX	RIABNI	47033		GPI-10 (2135186014)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #8 fills.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Riabni will be used in combination with chemotherapy (e.g., fludarabine, cyclophosphamide)
   - Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve for 6 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #3.

3. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Riabni will be used in combination with glucocorticoids (e.g., methylprednisolone, prednisone)
   - Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA

   If yes, **approve for 12 months by HICL or GPI-10 for #4 fills.**
   If no, continue to #4.

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RITUXIMAB-ARRX

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is currently using or has a contraindication to methotrexate
   - Riabni will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 for #2 fills.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB-ARRX

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, continue to #7.

7. Does the patient have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), Burkitt lymphoma (BL) (ICD-10 Group C83.7), Burkitt-like lymphoma (BLL) (ICD-10 Group C83.7) or mature B-cell acute leukemia (B-AL) (ICD-10 Group C91.A) and meet **ALL** of the following criteria?
   - The patient is 6 months to 17 years of age
   - Therapy is prescribed by or in consultation with an oncologist
   - Riabni will be used in combination with chemotherapy (e.g., CVP [cyclophosphamide-vincristine-prednisolone])
   - Riabni will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL, BL, BLL, or B-AL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #8.

8. Is the request for an FDA-approved indication **AND** Riabni will be used in combination with another chemotherapy agent(s)?
   [**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with Riabni. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB-ARRX

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-ARRX (Riabni)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
   2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   3. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
   4. Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
   5. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   6. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
   7. Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt- like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
   8. Riabni will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

B. If you have non-Hodgkin's lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin's lymphoma (a type of blood cancer)

C. If you have chronic lymphocytic leukemia, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. Riabni will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
   4. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia (a type of blood cancer)

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INITIAL CRITERIA (CONTINUED)

D. If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:
1. You are 2 years of age or older
2. Riabni will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
3. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis (conditions that affect the blood vessels)

E. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
4. You will NOT use Riabni concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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RITUXIMAB-ARRX

INITIAL CRITERIA (CONTINUED)

F. If you have moderate to severe pemphigus vulgaris, approval also requires:
1. You are 18 years of age or older
2. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris (a type of skin condition)

G. If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:
1. You are 6 months to 17 years of age
2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
3. Riabni will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
4. You will NOT use Riabni concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia (types of blood cancer)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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RITUXIMAB-ARRX

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - Riabni will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RITUXIMAB-ARRX

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-ARRX (Riabni)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
C. You will NOT use Riabni concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
D. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
        i. Enbrel (etanercept)
        ii. Adalimumab-ryvk/adalimumab-aaty
        iii. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
        iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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RITUXIMAB-ARRX

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Riabni and Rituxan.

REFERENCES

Riabni [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; June 2025.
Rituxan [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2021.

Created: 02/21
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB AND HYALURONIDASE HUMAN - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB/ HYALURONIDASE, HUMAN	RITUXAN HYCELA	44378		GPI-10 (2199000264)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of follicular lymphoma (FL) (ICD-10 Group C82) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has received or will receive at least one full dose of a rituximab product by intravenous infusion prior to the initiation of Rituxan Hycela
- Rituxan Hycela will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of FL

If yes, continue to #2.
If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
- The patient has relapsed or refractory FL
- The patient has previously untreated FL AND Rituxan Hycela will be used in combination with chemotherapy (e.g., CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CVP [cyclophosphamide, vincristine, prednisone])
- The patient has achieved a complete or partial response to rituximab in combination with chemotherapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
- The patient has non-progressing (including stable disease) FL AND Rituxan Hycela will be used after cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

If yes, **approve the 1,400 mg-23,400 units/11.7mL strength for 12 months by GPID or GPI-14.**

If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received or will receive at least one full dose of a rituximab product by intravenous infusion prior to the initiation of Rituxan Hycela
   - The patient has not been previously treated for DLBCL
   - Rituxan Hycela will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or another anthracycline-based chemotherapy regimen
   - Rituxan Hycela will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL

   If yes, **approve the 1,400 mg-23,400 units/11.7mL strength for 12 months by GPID or GPI-14.**
   If no, continue to #4.

4. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received or will receive at least one full dose of a rituximab product by intravenous infusion prior to the initiation of Rituxan Hycela
   - Rituxan Hycela will be used in combination with fludarabine and cyclophosphamide (FC)
   - Rituxan Hycela will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve the 1,600 mg-26,800 units/13.4mL strength for 12 months by GPID or GPI-14.**

   If no, continue to #5.

5. Is the request for an FDA-approved indication **AND** Rituxan Hycela will be used in combination with another chemotherapy agent(s)?
   [**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with Rituxan Hycela. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB AND HYALURONIDASE HUMAN - SQ (Rituxan Hycela)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Follicular lymphoma (FL: a type of blood cancer)
   2. Diffuse large B-cell lymphoma (DLBCL: a type of blood cancer)
   3. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   4. Rituxan Hycela will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

B. If you have follicular lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. You have received or will receive at least one full dose of a rituximab product by intravenous infusion (injection into the vein) before starting Rituxan Hycela
   3. You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of follicular lymphoma
   4. You meet ONE of the following:
      a. You have relapsed or refractory follicular lymphoma (cancer that has returned or does not fully respond to treatment)
      b. You have previously untreated follicular lymphoma AND Rituxan Hycela will be used in combination with chemotherapy (a type of cancer treatment, such as CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone], CVP [cyclophosphamide, vincristine, prednisone])
      c. You have achieved a complete or partial response to rituximab in combination with chemotherapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
      d. You have non-progressing (including stable disease) follicular lymphoma (cancer that is not worsening), AND Rituxan Hycela will be used after cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

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RITUXIMAB AND HYALURONIDASE HUMAN - SQ

GUIDELINES FOR USE (CONTINUED)

C. If you have diffuse large B-cell lymphoma, approval also requires:
1. You are 18 years of age or older
2. You have received or will receive at least one full dose of a rituximab product by intravenous infusion (injection into the vein) before starting Rituxan Hycela
3. You have not been previously treated for diffuse large B-cell lymphoma
4. Rituxan Hycela will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or another anthracycline-based chemotherapy regimen (a type of cancer treatment)
5. You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma

D. If you have chronic lymphocytic leukemia (CLL), approval also requires:
1. You are 18 years of age or older
2. You have received or will receive at least one full dose of a rituximab product by intravenous infusion (injection into the vein) before starting Rituxan Hycela
3. Rituxan Hycela will be used in combination with fludarabine and cyclophosphamide (FC)
4. You will NOT use Rituxan Hycela concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia

Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rituxan Hycela.

REFERENCES

Rituxan Hycela [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2021.

Created: 08/17
Effective: 03/10/25 Client Approval: 02/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB-PVVR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RITUXIMAB-PVVR	RUXIENCE	45899		GPI-10 (2135186060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of NHL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #8 fills.**
   If no, continue to #2.

2. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an oncologist
   - Ruxience will be used in combination with chemotherapy (e.g., fludarabine, cyclophosphamide)
   - Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CLL

   If yes, **approve for 6 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #3.

3. Does the patient have a diagnosis of granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (ICD-10 Group M31.3) or microscopic polyangiitis (MPA) (ICD-10 M31.7) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Ruxience will be used in combination with glucocorticoids (e.g., methylprednisolone, prednisone)
   - Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPA (Wegener's granulomatosis) or MPA

   If yes, **approve for 12 months by HICL or GPI-10 for #4 fills.**
   If no, continue to #4.

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient is currently using or has a contraindication to methotrexate
   - Ruxience will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #5.
   If no, continue to #6.

5. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 for #2 fills.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe pemphigus vulgaris (PV) (ICD-10 L10.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PV

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, continue to #7.

7. Does the patient have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), Burkitt lymphoma (BL) (ICD-10 Group C83.7), Burkitt-like lymphoma (BLL) (ICD-10 Group C83.7) or mature B-cell acute leukemia (B-AL) (ICD-10 Group C91.A) and meet **ALL** of the following criteria?
   - The patient is 6 months to 17 years of age
   - Therapy is prescribed by or in consultation with an oncologist
   - Ruxience will be used in combination with chemotherapy (e.g., CVP [cyclophosphamide-vincristine-prednisolone])
   - Ruxience will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of DLBCL, BL, BLL, or B-AL

   If yes, **approve for 12 months by HICL or GPI-10 for up to #6 fills.**
   If no, continue to #8.

8. Is the request for an FDA-approved indication **AND** Ruxience will be used in combination with another chemotherapy agent(s)?
   [**NOTE:** Please check claims history, MRF, etc. for combination chemotherapy agent(s). In addition, please refer to the label of the combination chemotherapy agent(s) to ensure the indication is to be used with Ruxience. Clinically appropriate to accept FDA approval in any of the combination chemotherapy agent(s) labels.]

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Non-Hodgkin's lymphoma (NHL: a type of blood cancer)
   2. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
   3. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) (a condition that affects the blood vessels)
   4. Microscopic polyangiitis (MPA: a condition that affects the blood vessels)
   5. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   6. Moderate to severe pemphigus vulgaris (PV: a type of skin condition)
   7. Previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL: a type of blood cancer), Burkitt lymphoma (BL: a type of blood cancer), Burkitt- like lymphoma (BLL: a type of blood cancer), or mature B-cell acute leukemia (B-AL: a type of blood cancer)
   8. Ruxience will be used in combination with another chemotherapy agent(s) for a Food and Drug Administration (FDA)-approved indication

B. If you have non-Hodgkin's lymphoma, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
   3. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-Hodgkin's lymphoma (a type of blood cancer)

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

C. If you have chronic lymphocytic leukemia, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
3. Ruxience will be used in combination with chemotherapy (such as fludarabine, cyclophosphamide)
4. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic lymphocytic leukemia (a type of blood cancer)

D. If you have granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis, approval also requires:
1. You are 2 years of age or older
2. Ruxience will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)
3. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of granulomatosis with polyangiitis (Wegener's granulomatosis) or microscopic polyangiitis (conditions that affect the blood vessels)

E. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You are currently using or have a contraindication to (harmful for you to use) methotrexate
4. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
5. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE standard of care medication: a conventional synthetic DMARD (disease-modifying antirheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

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RITUXIMAB-PVVR

INITIAL CRITERIA (CONTINUED)

6. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use)TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

F. If you have moderate to severe pemphigus vulgaris, approval also requires:
1. You are 18 years of age or older
2. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of pemphigus vulgaris (a type of skin condition)

G. If you have previously untreated advanced stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia, approval also requires:
1. You are 6 months to 17 years of age
2. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor)
3. Ruxience will be used in combination with chemotherapy (such as CVP [cyclophosphamide-vincristine-prednisolone])
4. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia (types of blood cancer)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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RITUXIMAB-PVVR

RENEWAL CRITERIA

NOTE: For the diagnoses of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL), chronic lymphocytic leukemia (CLL), granulomatosis with polyangiitis (GPA) Wegener's granulomatosis), microscopic polyangiitis (MPA), and moderate to severe pemphigus vulgaris (PV), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - Ruxience will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 for #3 fills.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RITUXIMAB-PVVR

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
C. You will NOT use Ruxience concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
D. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
        a. Enbrel (etanercept)
        b. Adalimumab-ryvk/adalimumab-aaty
        c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
        d. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
    2. You have tried a tumor necrosis factor (TNF) inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated that you cannot use a Janus kinase (JAK) inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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RITUXIMAB-PVVR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ruxience and Rituxan.

REFERENCES

Ruxience [Prescribing Information]. New York, NY: Pfizer Labs; June 2025.
Rituxan [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2021.

Created: 02/20
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST - FOAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		55119	GPI-14 (90230061003920)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seborrheic dermatitis (ICD-10 Group L21) **AND** meet the following criterion?
   - The patient is 9 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Has the patient had a trial of or contraindication to **ONE** of the following preferred agents?
   - High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   - Topical antifungal (e.g., ketoconazole, ciclopirox)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)

   If yes, **approve for 8 weeks by GPID or GPI-14.**
   If no, continue to #3.

3. Has the patient had a prior successful treatment with roflumilast foam?

   If yes, **approve for 8 weeks by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROFLUMILAST - FOAM

INITIAL CRITERIA (CONTINUED)

5. Has the patient had a trial of or contraindication to **ONE** of the following clinical standard of care agents?
   - High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   - Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment)

   If yes, **approve for 8 weeks by GPID or GPI-14.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROFLUMILAST - FOAM (Zoryve)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Seborrheic dermatitis (a type of skin condition)
      2. Plaque psoriasis (a type of skin condition)

   B. If you have seborrheic dermatitis, approval also requires:
      1. You are 9 years of age or older
      2. You meet ONE of the following:
         a. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
            i. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
            ii. Topical antifungal (such as ketoconazole, ciclopirox)
            iii. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
         b. You previously had a successful treatment with roflumilast foam

   C. If you have plaque psoriasis, approval also requires:
      1. You are 12 years of age or older
      2. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications:
         a. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
         b. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ROFLUMILAST - FOAM

RENEWAL CRITERIA

NOTE: For the diagnosis of seborrheic dermatitis, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient's plaque psoriasis involves the scalp and/or body
   - The patient has achieved or maintained clear or minimal disease

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROFLUMILAST - FOAM (Zoryve)** requires the following rule(s) be met for renewal:
   A. You have plaque psoriasis (a type of skin condition)
   B. Your plaque psoriasis (a type of skin condition) involves the scalp and/or body
   C. You have achieved or maintained clear or minimal disease

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES

Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; May 2025.

Created: 12/23
Effective: 05/28/26 Client Approval: 05/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.3% CREAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		52657	GPI-14 (90230061003730)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, continue to #2.
   If no, do no approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient had a trial of or contraindication to **ONE** of the following preferred agents?
   - High potency topical corticosteroid (e.g., triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (e.g., fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
   - Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Topical retinoid (e.g., tazarotene cream/gel)
   - Anthralin

   If yes, **approve for 2 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROFLUMILAST 0.3% CREAM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **ROFLUMILAST 0.3% CREAM (Zoryve)** requires the following rule(s) be met for approval:

A. You have plaque psoriasis (a type of skin condition)
B. You are 2 years of age or older
C. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
    1. High potency topical corticosteroid (such as triamcinolone acetonide 0.5% cream or ointment, halobetasol propionate 0.01% lotion) or a super-high potency topical corticosteroid (such as fluocinonide 0.1% cream, clobetasol propionate 0.05% cream or ointment)
    2. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
    3. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
    4. Topical retinoid (such as tazarotene cream/gel)
    5. Anthralin

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.3% CREAM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **ROFLUMILAST 0.3% CREAM (Zoryve)** requires the following rule(s) be met for renewal:
   A. You have plaque psoriasis (a type of skin condition)
   B. You have achieved or maintained clear or minimal disease

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RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES
Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; June 2026.

Created: 08/22
Effective: 07/15/26 Client Approval: 07/26 DMC Approval: 07/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.05% CREAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		58432	GPI-14 (90230061003710)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
- The patient is 2 to 5 years of age

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
- The patient had a trial of or contraindication to the clinical standard of care agent: a topical corticosteroid (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
- The patient had a trial of or contraindication to the preferred agent: a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])

If yes, **approve for 3 months by GPID or GPI-14**.
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROFLUMILAST 0.05% CREAM (Zoryve)** requires the following rule(s) be met for approval:
A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You are 2 to 5 years of age
C. You meet ONE of the following:
   1. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.05% CREAM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?

- The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

If yes, **approve for 12 months by GPID or GPI-14.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROFLUMILAST 0.05% CREAM (Zoryve)** requires the following rule(s) be met for renewal:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting dermatitis (a type of skin condition that returns and goes away), or facial/interdigital (between the fingers or toes) involvement

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES

Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; October 2025.

Created: 10/25
Effective: 05/28/26 Client Approval: 05/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.15% CREAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROFLUMILAST	ZORYVE		55978	GPI-14 (90230061003720)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
- The patient is 6 years of age or older

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
- The patient had a trial of or contraindication to the clinical standard of care agent: a topical corticosteroid (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
- The patient had a trial of or contraindication to the preferred agent: a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])

If yes, **approve for 3 months by GPID or GPI-14.**
If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROFLUMILAST 0.15% CREAM (Zoryve)** requires the following rule(s) be met for approval:
A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You are 6 years of age or older
C. You meet ONE of the following:
   1. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROFLUMILAST 0.15% CREAM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?

- The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

If yes, **approve for 12 months by GPID or GPI-14.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROFLUMILAST 0.15% CREAM (Zoryve)** requires the following rule(s) be met for renewal:

A. You have mild to moderate atopic dermatitis (a type of skin condition)
B. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting dermatitis (a type of skin condition that returns and goes away), or facial/interdigital (between the fingers or toes) involvement

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zoryve.

REFERENCES

Zoryve [Prescribing Information]. Westlake Village, CA: Arcutis Biotherapeutics, Inc.; July 2024.

Created: 07/24
Effective: 05/28/26 Client Approval: 05/26 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMIDEPSIN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROMIDEPSIN	ISTODAX	36898		GPI-10 (2153156000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cutaneous T-cell lymphoma (CTCL: also known as Mycosis Fungoides/Sezary Syndrome) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has a trial of or contraindication to Zolinza (vorinostat) AND is not able to tolerate oral medications
   - The patient has tried at least one form of systemic therapy (e.g., retinoids, interferons, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil) AND is able to tolerate oral medications

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROMIDEPSIN (Istodax)** requires the following rule(s) be met for approval:
   A. You have cutaneous T-cell lymphoma (CTCL: type of cancer that affects a certain type of immune system cells) also known as Mycosis Fungoides/Sezary Syndrome
   B. You are 18 years of age or older
   C. You meet ONE of the following:
      1. You had a trial of Zolinza (vorinostat) unless there is a medical reason why you cannot (contraindication) AND you are not able to tolerate oral medications
      2. You have tried at least one form of systemic therapy (such as retinoids, interferon, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil) AND you are able to tolerate oral medications

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ROMIDEPSIN (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Istodax.

REFERENCES

Istodax [Prescribing Information]. Celgene Corporation: Summit, NJ. July 2021.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 08/30/21
Created: 02/10
Client Approval: 08/21
P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMIPLOSTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROMIPLOSTIM	NPLATE	35798		GPI-10 (8240506000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ONE** of the following criteria?
   - The patient is 1 to 17 years of age AND has had ITP for at least 6 months
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: a corticosteroid or IV immunoglobulin, OR had an insufficient response to a splenectomy
   - Nplate will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Promacta [eltrombopag], Alvaiz [eltrombopag])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has a platelet count of less than 30 x 10^9/L
   - The patient has a platelet count of less than 50 x 10^9/L AND a prior bleeding event

   If yes, **approve all strengths for 4 months by GPID or GPI-14 as follows:**
   - **125mcg: no quantity limit.**
   - **250mcg: #8 per 28 days.**
   - **500mcg: #8 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROMIPLOSTIM

INITIAL CRITERIA (CONTINUED)

4. Is the request to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [HS-ARS])?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROMIPLOSTIM (Nplate)** requires the following rule(s) be met for approval:

   A. You meet ONE of the following:
      1. You have immune thrombocytopenia (ITP: a type of blood disorder)
      2. You will be using Nplate to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (doses that decrease bone marrow activity)

   B. If you have immune thrombocytopenia, approval also requires:
      1. You are 1 to 17 years of age with immune thrombocytopenia (ITP: a type of blood disorder) for at least 6 months, OR you are 18 years of age or older
      2. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a corticosteroid or intravenous (injection into the vein) immunoglobulin, OR you did not have a good enough response to a splenectomy (spleen removal)
      3. You will NOT use Nplate concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Promacta [eltrombopag], Alvaiz [eltrombopag])
      4. You meet ONE of the following:
         a. You have a platelet (a type of blood cell) count of less than 30 x 10^9/L
         b. You have a platelet (a type of blood cell) count of less than 50 x 10^9/L AND a prior bleeding event

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMIPLOSTIM

RENEWAL CRITERIA

NOTE: If the request is to increase survival in a patient acutely exposed to myelosuppressive doses of radiation, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of immune thrombocytopenia (ITP) (ICD-10 D69.3) and meet **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy, defined as having an improvement in platelet count from baseline OR a reduction in bleeding events
   - Nplate will NOT be used concurrently with other thrombopoietin receptor agonists (TPO-RAs) (e.g., Doptelet [avatrombopag], Promacta [eltrombopag], Alvaiz [eltrombopag])

   If yes, **approve all strengths for 12 months by GPID or GPI-14 as follows:**
   - **125mcg: no quantity limit.**
   - **250mcg: #8 per 28 days.**
   - **500mcg: #8 per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROMIPLOSTIM (Nplate)** requires the following rule(s) be met for renewal:
   A. You have immune thrombocytopenia (ITP: a type of blood disorder)
   B. You have shown a clinical response to therapy, defined as having an improvement in platelet (a type of blood cell) count from baseline (before starting Nplate) OR a decrease in bleeding events
   C. You will NOT use Nplate concurrently (at the same time) with other thrombopoietin receptor agonists (TPO-RAs, such as Doptelet [avatrombopag], Promacta [eltrombopag], Alvaiz [eltrombopag])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nplate.

REFERENCES

Nplate [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; March 2025.

Created: 10/08
Effective: 07/29/26 Client Approval: 07/26 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROMOSOZUMAB-AQQG (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROMOSOZUMAB-AQQG	EVENITY	45681		GPI-10 (3004486010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis and meet **ONE** of the following criteria?
   - The patient is at high risk for fractures defined as ONE of the following:
     - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
     - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
     - No prior treatment for osteoporosis AND FRAX score greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
   - The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
   - The patient had an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient received a total of 12 months of Evenity therapy?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.34mL per month.**

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ROMOSOZUMAB-AQQG (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROMOSOZUMAB-AQQG (Evenity)** requires the following rule(s) be met for approval:

A. You have postmenopausal osteoporosis (weak and brittle bones)
B. You have not received a total of 12 months or more of Evenity therapy
C. You meet ONE of the following criteria:
   1. You are at high risk for fractures defined as ONE of the following:
      a. History of osteoporotic (fragility, low trauma) fracture(s)
      b. 2 or more risk factors for fracture such as history of multiple recent low trauma fractures, bone marrow density [BMD] T-score (measurement of how high your risk for osteoporosis is) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.
      c. No prior treatment for osteoporosis AND FRAX score (test for your risk of fractures) greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
   2. You are unable to use oral therapy. Reasons include upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine
   3. You had an adequate trial of, intolerance to, or a contraindication to (medical reason why you cannot use) bisphosphonates such as Fosamax, Actonel, Boniva

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evenity.

REFERENCES

Evenity [Prescribing Information]. Thousand Oaks, CA: Amgen Inc; April 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/23
Created: 04/19
Client Approval: 03/23
P&T Approval: 02/17

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROPEGINTERFERON ALFA-2B-NJFT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROPEGINTERFERON ALFA-2B-NJFT	BESREMI	47669		GPI-10 (2170007750)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of polycythemia vera (ICD-10 D45) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or an oncologist

   If yes, **approve all formulations for 12 months by GPID or GPI-14 as follows:**
   - **500mcg/mL: #2mL per 28 days.**
   - **500mcg/0.5mL: #1mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of essential thrombocythemia (ICD-10 D47.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hematologist or an oncologist
   - The patient had a trial of or contraindication to the clinical standard of care agent: hydroxyurea
   - The patient had a trial of or contraindication to the preferred agent: Pegasys (peginterferon alfa-2a)
   - Besremi will NOT be used concurrently with another interferon (e.g., Pegasys [peginterferon alfa-2a]) or anagrelide

   If yes, **approve all formulations for 12 months by GPID or GPI-14 as follows:**
   - **500mcg/mL: #2mL per 28 days.**
   - **500mcg/0.5mL: #1mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ROPEGINTERFERON ALFA-2B-NJFT

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROPEGINTERFERON ALFA-2B-NJFT (Besremi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Polycythemia vera (a type of blood cancer)
   2. Essential thrombocythemia (a rare type of blood cancer)

B. If you have polycythemia vera, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or an oncologist (a type of cancer doctor)

C. If you have essential thrombocythemia, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or an oncologist (a type of cancer doctor)
   3. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: hydroxyurea
   4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Pegasys (peginterferon alfa-2a)
   5. You will NOT use Besremi concurrently (at the same time) with another interferon (such as Pegasys [peginterferon alfa-2a]) or anagrelide

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Besremi.

REFERENCES

Besremi [Prescribing Information]. Burlington, MA: PharmaEssentia, Corp., August 2026.

Created: 01/22 Maintenance: Yes
Effective: 09/16/26 Client Approval: 09/26 DMC Approval: 09/09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROSUVASTATIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROSUVASTATIN CALCIUM	EZALLOR SPRINKLE	25009		GPI-10 (3940006010)	BRAND = EZALLOR SPRINKLE

GUIDELINES FOR USE

1. Does the patient have a contraindication to or is unable to swallow rosuvastatin oral tablets?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient also requesting a zero-dollar cost share exception (the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10.**

3. Does the patient meet **ALL** of the following criteria?
   - The patient is between 40 to 75 years old
   - The requested quantity is within the low to moderate intensity daily dosage of 5mg to 10mg
   - The patient is NOT concurrently taking any of the below secondary prevention medications for cardiovascular disease:
     - Aspirin/dipyridamole (Aggrenox)
     - Clopidogrel (Plavix)
     - Dipyridamole
     - Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
     - Prasugrel (Effient)
     - Ticagrelor (Brilinta)
     - Ticlopidine
     - Vorapaxar (Zontivity)

   If yes, **approve for 12 months by GPID or GPI-14 at zero copay for all of the following:**
   - **5mg.**
   - **10mg.**

   If no, **approve for 12 months by HICL or GPI-10.**

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ROSUVASTATIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROSUVASTATIN (Ezallor Sprinkle)** requires the following rule(s) be met for approval:

A. You have a contraindication to (harmful for you to use) or are unable to swallow rosuvastatin oral tablets

B. Requests for zero-dollar cost share also requires the following:

1. You are between 40 to 75 years old
2. The requested quantity is within the low to moderate intensity daily dosage of 5mg to 10mg
3. You are NOT concurrently (at the same time) taking any of the following secondary prevention medications for cardiovascular disease (heart disease):
   a. Aspirin/dipyridamole (Aggrenox)
   b. Clopidogrel (Plavix)
   c. Dipyridamole
   d. Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
   e. Prasugrel (Effient)
   f. Ticagrelor (Brilinta)
   g. Ticlopidine
   h. Vorapaxar (Zontivity)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ezallor Sprinkle.

This guideline also applies to plans where the pharmacy benefit allows for coverage Ezallor Sprinkle at zero copay. The override criteria allow patient a zero copay by waiving the applicable cost-sharing to Ezallor Sprinkle, which is included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

Ezallor Sprinkle [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; February 2025.

U.S. Preventive Services Task Force [Final Summary]. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication. Updated August 2022. Available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/statin-use-in-adults-preventive-medication. Accessed October 2025.

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs. Accessed October 2025.

Created: 05/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ROZANOLIXIZUMAB-NOLI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROZANOLIXIZUMAB-NOLI	RYSTIGGO	49035		GPI-10 (9939827055)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a positive serologic test for anti-acetylcholine receptor antibody (AChR-Ab+) OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+)
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - Rystiggo will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Vyvgart [efgartigimod alfa-fcab], Imaavy [nipocalimab-aahu]), complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #36 mL per 42 days for 3 fills.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ROZANOLIXIZUMAB-NOLI

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ROZANOLIXIZUMAB-NOLI (Rystiggo)** requires the following rule(s) be met for approval:

A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
D. You have a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+) OR anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+) (a type of blood test that shows you have myasthenia gravis)
E. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
F. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
G. You will NOT use Rystiggo concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Imaavy [nipocalimab-aahu]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
H. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
    2. You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ROZANOLIXIZUMAB-NOLI

RENEWAL CRITERIA

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Rystiggo will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Vyvgart [efgartigimod alfa-fcab], Imaavy [nipocalimab-aahu]), complement inhibitor (e.g., Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (e.g., Uplizna [inebilizumab-cdon]) for the treatment of gMG

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #36 mL per 42 days for 6 fills.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ROZANOLIXIZUMAB-NOLI (Rystiggo)** requires the following rule(s) be met for renewal:
   A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   B. You have had clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   C. You will NOT use Rystiggo concurrently (at the same time) with another neonatal Fc receptor blocker (such as Vyvgart [efgartigimod alfa-fcab], Imaavy [nipocalimab-aahu]), complement inhibitor (such as Soliris [eculizumab], Zilbrysq [zilucoplan]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rystiggo.

REFERENCES

Rystiggo [Prescribing Information]. Smyrna, GA: UCB, Inc.; June 2024.

Created: 07/23
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUCAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUCAPARIB CAMSYLATE	RUBRACA	44002		GPI-10 (2153557020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent epithelial ovarian (ICD-10 Groups C56, C79.6), fallopian tube (ICD-10 Group C57.0), or primary peritoneal cancer (ICD-10 Group C48), and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious BRCA mutation (germline and/or somatic)
   - The patient is in complete or partial response to platinum-based chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2 and C61) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a deleterious BRCA mutation (germline and/or somatic) based on an FDA-approved companion diagnostic for Rubraca
   - The patient has been treated with an androgen receptor-directed therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient previously had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
   - The requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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RUCAPARIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUCAPARIB (Rubraca)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (types of reproductive system cancers that has returned)
   2. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life)
   3. You are in complete or partial response to platinum-based chemotherapy (a type of therapy to treat cancer)

C. If you have metastatic castration-resistant prostate cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer has a deleterious BRCA mutation (germline and/or somatic) (a type of gene mutation that is passed on from parent to child and/or acquired during life) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Rubraca
   3. You have been treated with an androgen receptor-directed therapy (type of therapy to treat cancer)
   4. You meet ONE of the following:
      a. You previously received a bilateral orchiectomy (removal of both testicles)
      b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
      c. Rubraca will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rubraca.

REFERENCES

Rubraca [Prescribing Information]. Boulder, CO: Clovis Oncology, Inc.; December 2025.

Created: 12/16
Effective: 01/19/26 Client Approval: 01/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUXOLITINIB PHOSPHATE	JAKAFI, JAKAFI XR	38202		GPI-10 (2153756020)	ROUTE ≠ TOPICAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis (ICD-10 D75.81), including primary myelofibrosis (ICD-10 D47.1), post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for Jakafi?

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of Jakafi.**
   If no, continue to #3.

3. Is the request for Jakafi XR **AND** the patient had a trial of or contraindication to the preferred agent: Jakafi?

   If yes, **approve for 6 months by GPID for all strengths of Jakafi XR or by GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of polycythemia vera (ICD-10 D45) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the clinical standard of care agent: hydroxyurea

   If yes, continue to #7.
   If no, continue to #5.

5. Does the patient have a diagnosis of steroid-refractory acute graft-versus-host disease (ICD-10 D89.810, D89.812) **AND** meet the following criterion?
   - The patient is 12 years of age or older

   If yes, continue to #7.
   If no, continue to #6.

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RUXOLITINIB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of chronic graft-versus-host disease (cGVHD) (ICD-10 D89.811, D89.812) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has failed at least ONE line of systemic therapy (e.g., prednisone, methotrexate, mycophenolate mofetil)
   - The requested medication will NOT be used concurrently with Rezurock (belumosudil), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the request for Jakafi?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of Jakafi.**
   If no, continue to #8.

8. Is the request for Jakafi XR **AND** the patient had a trial of or contraindication to the preferred agent: Jakafi?

   If yes, **approve for 12 months by GPID for all strengths of Jakafi XR or by GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB (Jakafi, Jakafi XR)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis (types of blood cancer)
      2. Polycythemia vera (a type of blood cancer)
      3. Steroid-refractory acute graft-versus-host disease (a type of short-term immune disorder that did not respond to a type of treatment)
      4. Chronic graft-versus-host disease (a type of long-term immune disorder)

   (Initial denial text continued on next page)

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RUXOLITINIB

INITIAL CRITERIA (CONTINUED)

B. If you have intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, approval also requires:
1. You are 18 years of age or older
2. If the request is for Jakafi XR (extended-release), approval also requires you have tried or have a contraindication to (harmful for you to use) the preferred medication: Jakafi (immediate release)

C. If you have polycythemia vera, approval also requires:
1. You are 18 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: hydroxyurea
3. If the request is for Jakafi XR (extended-release), approval also requires you have tried or have a contraindication to (harmful for you to use) the preferred medication: Jakafi (immediate release)

D. If you have steroid-refractory acute graft-versus-host disease, approval also requires:
1. You are 12 years of age or older
2. If the request is for Jakafi XR (extended-release), approval also requires you have tried or have a contraindication to (harmful for you to use) the preferred medication: Jakafi (immediate release)

E. If you have chronic graft-versus-host disease, approval also requires:
1. You are 12 years of age or older
2. You have failed at least ONE line of systemic therapy (treatment that targets the entire body, such as prednisone, methotrexate, mycophenolate mofetil)
3. You will NOT use the requested medication concurrently (at the same time) with Rezurock (belumosudil), Niktimvo (axatilimab-csfr), or Imbruvica (ibrutinib)
4. If the request is for Jakafi XR (extended-release), approval also requires you have tried or have a contraindication to (harmful for you to use) the preferred medication: Jakafi (immediate release)

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RUXOLITINIB

RENEWAL CRITERIA

NOTE: For the diagnoses of polycythemia vera, steroid-refractory acute graft-versus-host disease, or chronic graft-versus-host disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis (ICD-10 D75.81), including primary myelofibrosis (ICD-10 D47.1), post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown symptom improvement by meeting **ONE** of the following criteria?
   - The patient has had at least a 50% reduction in total symptom score (e.g., Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
   - The patient has had at least a 50% reduction in palpable spleen length
   - The patient has had a spleen volume reduction of at least 35% from baseline

   If yes, **approve for 12 months by GPID for all strengths of Jakafi or Jakafi XR or by GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB (Jakafi, Jakafi XR)** requires the following rule(s) be met for renewal:
   A. You have intermediate or high-risk myelofibrosis, which includes primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis (types of blood cancer)
   B. You have shown symptom improvement by meeting ONE of the following:
      1. You have had at least a 50% reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form Total Symptom Score [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0)
      2. You have had at least a 50% reduction in palpable (can be felt by external examination) spleen length
      3. You have had a spleen volume reduction of at least 35% from baseline (before treatment)

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RUXOLITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jakafi.

REFERENCES

Jakafi [Prescribing Information]. Wilmington, DE. Incyte Corporation; May 2026.

Created: 12/11
Effective: 09/04/26 Client Approval: 09/26 DMC Approval: 08/18/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RUXOLITINIB TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RUXOLITINIB PHOSPHATE	OPZELURA	38202		GPI-10 (9027206050)	ROUTE ≠ ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient is NOT immunocompromised

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to the clinical standard of care agent: a topical corticosteroid (e.g., halobetasol, triamcinolone, fluocinonide)
   - The patient had a trial of or contraindication to the preferred agent: a topical non-steroidal immunomodulating agent (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])

   If yes, **approve for 3 months by GPID or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of nonsegmental vitiligo (ICD-10 L80) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has depigmented areas covering 10% or less of total body surface area (BSA)
   - The patient had a trial of or contraindication to ONE of the following clinical standard of care agents: a topical corticosteroid (e.g., halobetasol, triamcinolone, fluocinonide) OR a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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RUXOLITINIB TOPICAL

INITIAL CRITERIA (CONTINUED)

4. Will Opzelura be used concurrently with **ANY** of the following?
   - Other non-steroid topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)])
   - Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   - Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   - Potent immunosuppressants (e.g., azathioprine, cyclosporine)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 6 months by GPID or GPI-10.**

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Mild to moderate atopic dermatitis (a type of skin condition)
      2. Nonsegmental vitiligo (a type of skin condition)
   B. If you have mild to moderate atopic dermatitis, approval also requires:
      1. You are 2 years of age or older
      2. You are NOT immunocompromised (weak immune system)
      3. You meet ONE of the following:
         a. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide)
         b. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a topical non-steroidal immunomodulating medication (such as Elidel [pimecrolimus], Protopic [tacrolimus])

   (Initial denial text continued on the next page)

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RUXOLITINIB TOPICAL

INITIAL CRITERIA (CONTINUED)

C. If you have nonsegmental vitiligo, approval also requires:

1. You are 12 years of age or older
2. You have depigmented (lightening of the skin) areas covering 10% or less of your total body surface area (BSA)
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications: a topical corticosteroid (such as halobetasol, triamcinolone, fluocinonide) or a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])
4. You will NOT use Opzelura concurrently (at the same time) with ANY of the following:
   a. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
   b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
   c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
   d. Potent immunosuppressants (such as azathioprine, cyclosporine)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RUXOLITINIB TOPICAL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of mild to moderate atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
- The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

If yes, **approve for 12 months by GPID or GPI-10**.
If no, continue to #2.

2. Does the patient have a diagnosis of nonsegmental vitiligo (ICD-10 L80) **AND** meet the following criterion?
- The patient has experienced or maintained clinically meaningful repigmentation

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Will Opzelura be used concurrently with **ANY** of the following?
- Other non-steroid topicals (e.g., calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 inhibitors [e.g., Eucrisa (crisaborole), Zoryve (roflumilast)])
- Systemic therapeutic biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
- Other JAK inhibitors (e.g., Rinvoq [upadacitinib], Cibinqo [abrocitinib])
- Potent immunosuppressants (e.g., azathioprine, cyclosporine)

If yes, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, **approve for 12 months by GPID or GPI-10.**

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RUXOLITINIB TOPICAL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RUXOLITINIB TOPICAL (Opzelura)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Mild to moderate atopic dermatitis (a type of skin condition)
   2. Nonsegmental vitiligo (a type of skin condition)

B. If you have mild to moderate atopic dermatitis, renewal also requires:
   1. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting dermatitis (a type of skin condition that returns and goes away), or facial/interdigital (between the fingers or toes) involvement

C. If you have nonsegmental vitiligo, renewal also requires:
   1. You have experienced or maintained clinically meaningful repigmentation (recoloration of the skin after loss in color)
   2. You will NOT use Opzelura concurrently (at the same time) with ANY of the following:
      a. Other non-steroidal topicals (such as calcineurin inhibitors [such as Elidel (pimecrolimus), Protopic (tacrolimus)], PDE-4 [phosphodiesterase-4] inhibitors [such as Eucrisa (crisaborole), Zoryve (roflumilast)])
      b. Systemic therapeutic biologics (such as Dupixent [dupilumab], Adbry [tralokinumab-ldrm])
      c. Other JAK (Janus kinase) inhibitors (such as Rinvoq [upadacitinib], Cibinqo [abrocitinib])
      d. Potent immunosuppressants (such as azathioprine, cyclosporine)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Opzelura.

REFERENCES

Opzelura [Prescribing Information]. Wilmington, DE: Incyte, Corporation; September 2025.

Created: 09/21
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SACITUZUMAB GOVITECAN-HZIY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SACITUZUMAB GOVITECAN-HZIY	TRODELVY	46478		GPI-10 (2155106540)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic breast cancer (ICD-10 Group C50)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's cancer triple-negative and the patient meets **ONE** of the following criteria?
   - The patient is not a candidate for programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor based therapy
   - Trodelvy will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph), AND the patient's tumor expresses programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) of at least 10], as determined by an FDA-authorized test
   - The patient has received two or more prior systemic therapies (e.g., docetaxel, paclitaxel), at least one of them for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient's cancer hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) and the patient meets **ALL** of the following criteria?
   - The patient has received endocrine-based therapy (e.g., tamoxifen, Arimidex [anastrozole])
   - The patient has received at least two additional systemic therapies (e.g., Enhertu [fam-trastuzumab deruxtecan-nxki], Talzenna [talazoparib]) in the metastatic setting

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SACITUZUMAB GOVITECAN-HZIY

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline named **SACITUZUMAB GOVITECAN-HZIY (Trodelvy)** requires the following rule(s) be met for approval:

A. You have unresectable locally advanced or metastatic breast cancer (a type of breast cancer that cannot be surgically removed and has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
B. You meet ONE of the following:
    1. Your breast cancer is triple negative (TNBC: a type of breast cancer that does not have three receptors); AND you are not a candidate for programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor based therapy (a type of cancer treatment)
    2. Your breast cancer is triple negative (TNBC: a type of breast cancer that does not have three receptors); Trodelvy will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph); AND your tumor has programmed death-ligand 1 (PD-L1: a type of protein) [Combined Positive Score (CPS) of at least 10], as determined by a Food and Drug Administration (FDA)-authorized test
    3. Your breast cancer is triple negative (TNBC: a type of breast cancer that does not have three receptors); AND you have tried two or more previous systemic therapies (treatment that targets the entire body such as docetaxel, paclitaxel), at least one of them for metastatic disease (disease that has spread to other parts of the body)
    4. Your breast cancer is hormone receptor (HR: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative (IHC 0, IHC 1+ or IHC 2+/ISH- [a type of lab test]); you have received endocrine (hormone)-based therapy (such as tamoxifen, Arimidex [anastrozole]); AND you have received at least two additional systemic therapies (treatment that targets the entire body such as Enhertu [fam-trastuzumab deruxtecan-nxki], Talzenna [talazoparib]) in the metastatic setting (disease has spread to other parts of the body)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trodelvy.

REFERENCES

Trodelvy [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; June 2026.

Created: 04/20
Effective: 07/15/26 Client Approval: 07/26 DMC Approval: 07/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SACROSIDASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SACROSIDASE	SUCRAID	18554		GPI-10 (5120006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID) (ICD-10 E74.31), and meet **ALL** of the following criteria?
   - The patient is 5 months of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist or medical geneticist
   - The patient has tried to manage CSID by adhering to a sucrose-free/low sucrose diet
   - The patient is experiencing symptoms, such as frequent watery diarrhea, abdominal pain/cramping, bloating, gas, dyspepsia, failure to thrive, weight loss, nausea and vomiting
   - The patient/caregiver will adhere to any necessary diet restrictions while on Sucraid

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

2. Is the patient's diagnosis confirmed by **ONE** of the following?
   - Small bowel biopsy
   - Sucrose breath test
   - Genetic test

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SACROSIDASE (Sucraid)** requires the following rule be met for approval:
   A. You have sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (a type of genetic digestive condition)
   B. You are 5 months of age or older
   C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or medical geneticist (doctor who treats gene disorders)
   D. You have tried to manage CSID (congenital sucrase-isomaltase deficiency: a type of genetic digestive condition) by keeping up with a sucrose-free/low sucrose diet (a type of diet)

   (Initial denial text continued on next page)

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SACROSIDASE

INITIAL CRITERIA (CONTINUED)

E. You are experiencing symptoms, such as frequent watery diarrhea, abdominal pain/cramping, bloating, gas, dyspepsia (pain or discomfort in the stomach area), failure to thrive, weight loss, nausea and vomiting
F. You or your caregiver will keep up with any necessary diet restrictions while on Sucraid
G. Your diagnosis is confirmed by ONE of the following:
    1. Small bowel biopsy (removal of cells or tissue from the body for examination)
    2. Sucrose (a type of sugar) breath test
    3. Genetic test

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SACROSIDASE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID) (ICD-10 E74.31) **AND** meet the following criterion?
   - The patient has experienced or maintained improvement on treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SACROSIDASE (Sucraid)** requires the following rule(s) be met for renewal:
   A. You have sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (a type of genetic digestive condition)
   B. You have experienced or maintained improvement on treatment

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sucraid.

REFERENCES

Sucraid [Prescriber Information]. Vero Beach, FL: QOL Medical, LLC.; December 2025.

Created: 05/12
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SARGRAMOSTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SARGRAMOSTIM	LEUKINE	06074		GPI-10 (8240205000)	

GUIDELINES FOR USE

1. Is therapy prescribed by or in consultation with a hematologist or oncologist?

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**

   If no, continue to #2.

2. Has the patient undergone or is undergoing induction chemotherapy for acute myeloid leukemia (AML) (ICD-10 Group C92.0) **AND** meet the following criterion?
   - The patient is 55 years of age or older

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**

   If no, continue to #3.

3. Is the patient undergoing autologous hematopoietic stem cell transplantation and meet **ALL** of the following criterion?
   - The patient has cancer
   - The patient is 18 years of age or older

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**

   If no, continue to #4.

4. Has the patient undergone or is undergoing autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation and meet **ALL** of the following criteria?
   - The patient has non-Hodgkin's lymphoma (NHL) (ICD-10 Group C85), acute lymphoblastic leukemia (ALL) (ICD-10 Group C91.0), or Hodgkin's lymphoma (HL) (ICD-10 Group C81)
   - The patient is 2 years of age or older

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**

   If no, continue to #5.

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SARGRAMOSTIM

GUIDELINES FOR USE (CONTINUED)

5. Is the patient undergoing allogeneic bone marrow transplantation from an HLA-matched related donor **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**

   If no, continue to #6.

6. Has the patient undergone allogeneic or autologous bone marrow transplantation and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's neutrophil recovery is delayed or has failed

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**

   If no, continue to #7.

7. Is the patient acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])?

   If yes, **approve by HICL or GPI-10 for 3 months or requested duration of treatment up to 1 year.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SARGRAMOSTIM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SARGRAMOSTIM (Leukine)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
   2. You have undergone or are undergoing induction chemotherapy (you are starting cancer treatment or receiving treatment following initial therapy) for acute myeloid leukemia (AML: type of blood cancer) AND you are 55 years of age or older
   3. You are undergoing autologous hematopoietic stem cell transplantation (a type of procedure to replace damaged bone marrow with your own health blood-forming cells) for cancer AND you are 18 years of age or older
   4. You have undergone or are undergoing autologous peripheral blood progenitor cell or bone marrow transplantation (procedures to get healthy blood-forming cells) for non-Hodgkin's lymphoma (NHL: a type of blood cancer), acute lymphoblastic leukemia (ALL: type of blood cancer), or Hodgkin's lymphoma (a type of blood cancer), AND you are 2 years of age or older
   5. You are undergoing allogeneic bone marrow transplantation from human leukocyte antigen (HLA: a type of protein)-matched related donor (a type of procedure to get healthy blood-forming cells) AND you are 2 years of age or older
   6. You have undergone allogeneic or autologous bone marrow transplantation (procedure to get healthy blood-forming cells), your neutrophil (a type of white blood cell) recovery is delayed or has failed, AND you are 2 years of age or older
   7. You are acutely exposed to myelosuppressive doses (doses that suppress bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS: an illness that happens after whole body radiation])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leukine.

REFERENCES

Leukine [Prescribing Information]. Lexington, MA: Partner Therapeutics, Inc.; August 2023.

Created: 02/03
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 04/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SARILUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SARILUMAB	KEVZARA	44183		GPI-10 (6650006000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SARILUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polymyalgia rheumatica (PMR) (ICD-10 M35.3) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient had an inadequate response to corticosteroids (e.g., prednisone) or cannot tolerate a corticosteroid taper
- Kevzara will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of PMR

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
- The patient weighs at least 63 kg (138 lbs)
- Therapy is prescribed by or in consultation with a rheumatologist
- Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pJIA
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Adalimumab-ryvk/adalimumab-aaty
  - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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SARILUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polymyalgia rheumatica (PMR: an inflammatory disorder causing muscle pain and stiffness)
   3. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease modifying anti-rheumatic drug), such as methotrexate dose of at least 20 mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You meet ONE of the following:
      a. You have tried or have a contraindication to TWO of the following preferred medications:
         i. Enbrel (etanercept)
         ii. Adalimumab-ryvk/adalimumab-aaty
         iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      b. You have tried a TNF inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

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SARILUMAB

INITIAL CRITERIA (CONTINUED)

C. If you have polymyalgia rheumatica, approval also requires:
1. You are 18 years of age or older
2. You had an inadequate response (drug did not work) to corticosteroids (such as prednisone) or cannot tolerate a corticosteroid taper
3. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polymyalgia rheumatica (an inflammatory disorder causing muscle pain and stiffness)

D. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You weigh at least 63 kilograms (138 pounds)
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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SARILUMAB

RENEWAL CRITERIA

NOTE: For the diagnosis of polymyalgia rheumatica (PMR), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following?
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
   - The patient has tried a TNF inhibitor (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SARILUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - Kevzara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g. JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE- 4 inhibitor) for the treatment of pJIA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   NOTE: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SARILUMAB (Kevzara)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)

   B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
      2. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

   (Renewal denial text continued on next page)

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SARILUMAB

RENEWAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Adalimumab-ryvk/adalimumab-aaty
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      iv. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   b. You have tried a TNF inhibitor (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (Janus kinase inhibitor such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancer), and serious cardiovascular (heart-related) events

C. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:

1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Kevzara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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SARILUMAB

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Kevzara.

REFERENCE
Kevzara [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; June 2024.

Created: 11/16
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 01/25

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SATRALIZUMAB-MWGE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SATRALIZUMAB-MWGE	ENSPRYNG	46781		GPI-10 (9940507040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist or ophthalmologist
   - The patient has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
   - Enspryng will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have at least **ONE** of the following core clinical characteristics?
   - Optic neuritis
   - Acute myelitis
   - Area postrema syndrome
   - Acute brainstem syndrome
   - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
   - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #2mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #1mL per 28 days (enter a start date 2 days BEFORE the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SATRALIZUMAB-MWGE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SATRALIZUMAB-MWGE (Enspryng)** requires the following rule(s) be met for approval:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or ophthalmologist (a type of eye doctor)
D. You have a positive serologic (blood) test for anti-aquaporin-4 (AQP4: a type of protein) antibodies
E. You will NOT use Enspryng concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])
F. You have at least ONE of the following core clinical characteristics:
    1. Optic neuritis (a type of brain disorder)
    2. Acute myelitis (a type of brain disorder)
    3. Area postrema syndrome (a type of brain disorder)
    4. Acute brainstem syndrome (a type of brain disorder)
    5. Symptomatic narcolepsy (a type of sleep condition) or acute diencephalic clinical syndrome (tumor in a part of the brain) with NMOSD-typical diencephalic magnetic resonance imaging (MRI: a type of imaging lab) lesions (affected areas)
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SATRALIZUMAB-MWGE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (ICD-10 G36.0) and meet **ALL** of the following criteria?
   - The patient had a reduction in relapse frequency from baseline
   - Enspryng will NOT be used concurrently with another NMOSD agent (e.g., Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SATRALIZUMAB-MWGE (Enspryng)** requires the following rule(s) be met for renewal:
   A. You have neuromyelitis optica spectrum disorder (NMOSD: a type of brain disorder)
   B. You have experienced a reduction in relapse frequency from baseline (before treatment)
   C. You will NOT use Enspryng concurrently (at the same time) with another NMOSD medication (such as Rituxan [rituximab], Uplizna [inebilizumab-cdon], Ultomiris [ravulizumab-cwvz], Soliris [eculizumab])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enspryng.

REFERENCES

Enspryng [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2022.

Created: 08/20
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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SEBELIPASE ALFA (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEBELIPASE ALFA	KANUMA	42747		GPI-10 (3090636000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Therapy is prescribed by or given in consultation with an endocrinologist, hepatologist, gastroenterologist, medical geneticist, or lipidologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a diagnosis of rapidly progressive lysosomal acid lipase (LAL) deficiency presenting within the first 6 months of life (also known as Wolman Disease), as confirmed by the presence of clinical features (e.g., hepatomegaly, elevated serum transaminases, dyslipidemia, splenomegaly) and meets **ONE** of the following criteria?
   - A blood test indicating low or absent levels of LAL enzyme activity
   - A dried blood spot test indicating low or absent LAL enzyme activity
   - A genetic test indicating the bi-allelic presence of altered LIPA gene(s)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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SEBELIPASE ALFA (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life and not considered rapidly progressive (also known as cholesteryl ester storage disease (CESD)), as confirmed by the presence of clinical features (e.g., hepatomegaly, elevated serum transaminases, dyslipidemia, splenomegaly) and meets **ONE** of the following criteria?
   - A blood test indicating low or absent levels of LAL enzyme activity
   - A dried blood spot test indicating low or absent LAL enzyme activity
   - A genetic test indicating the bi-allelic presence of altered LIPA gene(s)

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the patient has a documented improvement in ONE of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency while on therapy with Kanuma:
   - A relative reduction from baseline in any one of the following lipid levels (LDL-c, non-HDL-c, or triglycerides).
   - Normalization of aspartate aminotransferase (AST) based on age- and gender-specific normal ranges.
   - A decrease in liver fat content compared to baseline assessed by abdominal imaging (e.g., multi-echo gradient echo [MEGE] MRI).

   Any one of the following baseline measurements will be required to assess renewal criteria: lipids (LDL-c, Non-HDL-c, or triglycerides), aspartate aminotransferase (AST), or MEGE MRI.

   If no, do not approve.
   INTIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SEBELIPASE ALFA (Kanuma)** requires the following rule(s) be met for approval:
   A. You have lysosomal acid lipase (LAL) deficiency (inherited condition where your body cannot breakdown and use fats and cholesterol), as confirmed by the presence of clinical features such as hepatomegaly (enlarged liver), elevated serum transaminases (types of enzymes), dyslipidemia (abnormal levels of fats), splenomegaly (enlarge spleen)
   B. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor), hepatologist (liver specialist), gastroenterologist (digestive system doctor), medical geneticist, or lipidologist (cholesterol management specialist)
   (Initial denial text continued on next page)

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SEBELIPASE ALFA (NSA)

INITIAL CRITERIA (CONTINUED)

C. You meet ONE of the following:
   1. A blood test indicating low or absent levels of lysosomal acid lipase enzyme activity
   2. A dried blood spot test indicating low or absent lysosomal acid lipase enzyme activity
   3. A genetic test indicating the bi-allelic presence of altered LIPA gene(s) (you have a change in a gene that provides instructions for producing an enzyme called lysosomal acid lipase)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life and not considered rapidly progressive?

   If yes, continue to #2.
   If no, do not approve.
   RENEWAL DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have documented improvement in **ONE** of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency during the past 6 months?
   - A relative reduction from baseline in any one of the following lipid levels (LDL-c, Non-HDL-c, or triglycerides)
   - Normalization of aspartate aminotransferase (AST) based on age- and gender-specific normal ranges
   - A decrease in liver fat content compared to baseline assessed by abdominal imaging (e.g., multi-echo gradient echo [MEGE] MRI)

   If yes, **approve for all requested strengths for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: See the denial text at the end of the guideline.

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SEBELIPASE ALFA (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEBELIPASE ALFA (Kanuma)** requires the following rule(s) be met for renewal:

A. You have lysosomal acid lipase (LAL) deficiency (inherited condition where your body cannot breakdown and use fats and cholesterol) presenting after the first 6 months of life and not considered rapidly progressive (getting worse)
B. You have documented improvement in ONE of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency during the past 6 months:
    1. A relative reduction from baseline in any one of the following lipid levels (fat lab measurements such as LDL-c, Non-HDL-c, or triglycerides)
    2. Normalization of aspartate aminotransferase (AST: type of liver enzyme) based on age- and gender-specific normal ranges
    3. A decrease in liver fat content compared to baseline assessed by abdominal imaging such as multi-echo gradient echo [MEGE] MRI

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kanuma.

REFERENCES

Kanuma [Prescribing Information]. Cheshire, CT: Alexion Pharmaceuticals, Inc., December 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 12/15
Client Approval: 04/20
P&T Approval: 02/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEBETRALSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEBETRALSTAT	EKTERLY	50678		GPI-10 (8584005000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?
- The patient is 12 years of age or older
- Ekterly will be used for the treatment of acute attacks of hereditary angioedema
- Therapy is prescribed by or in consultation with an allergist, immunologist, hematologist, or pulmonologist
- Ekterly will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have Type I or II HAE **AND** meet the following criterion?
- The diagnosis is confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q

If yes, **approve for 12 months by HICL or GPI-10.**
If no, continue to #3.

3. Does the patient have HAE-nC1INH (Type III HAE) as confirmed by **ALL** of the following criteria?
- The patient has recurrent, non-urticarial angioedema involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated HAE AND the attacks cannot be explained by histaminergic/urticarial angioedema
- Other causes of angioedema have been excluded, including ACE-inhibitor/ARB-associated angioedema, acquired C1-INH deficiency, and mast-cell/histaminergic angioedema

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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SEBETRALSTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEBETRALSTAT (Ekterly)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You are 12 years of age or older
C. Ekterly will be used for the treatment of acute (sudden and severe) attacks of hereditary angioedema (HAE: a type of gene condition with severe body swelling)
D. Therapy is prescribed by or in consultation with an allergist (a type of allergy doctor), immunologist (a type of immune system doctor), hematologist (a type of blood doctor), or pulmonologist (lung/breathing doctor)
E. You will NOT use Ekterly concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])
F. You meet ONE of the following:
    1. You have Type I or II hereditary angioedema (a type of gene condition with severe body swelling), as confirmed by ONE of the following complement tests: C1-INH protein levels, C4 protein levels, C1-INH functional levels, C1q (types of lab tests)
    2. You have HAE-nC1INH (hereditary angioedema with normal C1 inhibitor) (Type III hereditary angioedema) (a type of gene condition with severe body swelling) as confirmed by ALL of the following:
        a. You have recurrent (condition continues to return), non-urticarial angioedema (a type of swelling without hives) involving the skin, gastrointestinal tract, or airway, consistent with bradykinin-mediated hereditary angioedema (a type of gene condition with severe body swelling) AND the attacks cannot be explained by histaminergic/urticarial angioedema (a type of swelling due to an allergic reaction)
        b. Other causes of angioedema (a type of swelling) have been ruled out, including angiotensin-converting enzyme (ACE)-inhibitor/angiotensin receptor blocker (ARB)-associated angioedema (a type of swelling due to types of medications), acquired C1-INH deficiency (a type of condition that causes swelling), and mast-cell/histaminergic angioedema (a type of swelling due to an allergic reaction)

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SEBETRALSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) (ICD-10 D84.1) and meet **ALL** of the following criteria?

- The patient has experienced a reduction in the severity or duration of HAE attacks
- Ekterly will NOT be used concurrently with other agents used for the treatment of acute HAE attacks (e.g., Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEBETRALSTAT (Ekterly)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: a type of gene condition with severe body swelling)
B. You have experienced a reduction (decrease) in the severity or duration of hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks
C. You will NOT use Ekterly concurrently (at the same time) with other medications used for the treatment of acute (sudden and severe) hereditary angioedema (HAE: a type of gene condition with severe body swelling) attacks (such as Firazyr [icatibant], Berinert [C1 esterase inhibitor], Ruconest [C1 esterase inhibitor], Kalbitor [ecallantide])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ekterly.

REFERENCES

Ekterly [Prescribing Information]. Cambridge, MA: KalVista Pharmaceuticals, Inc.; July 2025.

Created: 07/25
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SECUKINUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SECUKINUMAB	COSENTYX	41715		GPI-10 (9025057500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, face, or scalp
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 11 years of age AND had a trial of or contraindication to FOUR of the following preferred agents: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast)
   - The patient is 12 to 17 years of age AND had a trial of or contraindication to FOUR of the following preferred agents: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast), Icotyde (icotrokinra)
   - The patient is 18 years of age or older AND had a trial of or contraindication to FOUR of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Enbrel (etanercept)
     - Otezla (apremilast)
     - Taltz (ixekizumab)
     - Sotyktu (deucravacitinib)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Icotyde (icotrokinra)

     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the following strengths:**
     - **75mg/0.5mL: #0.5mL per 28 days.**
     - **150mg/mL: #1mL per 28 days.**
     - **300mg/2mL: #2mL per 28 days.**

     (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
     - **75mg/0.5mL: #2mL per 28 days.**
     - **150mg/mL: #4mL per 28 days.**
     - **300mg/2mL: #8mL per 28 days.)**

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, continue to #5.
If no, continue to #7.

5. Does the patient meet **ONE** of the following criteria?
- The patient is 2 to 5 years of age AND had a trial of or contraindication to ONE of the following preferred agents:
  - Enbrel (etanercept)
  - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])
- The patient is 6 to 17 years of age AND had a trial of or contraindication to THREE of the following preferred agents:
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])

[**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the following strengths:**
- **75mg/0.5mL: #0.5mL per 28 days.**
- **150mg/mL: #1mL per 28 days.**

(Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
- **75mg/0.5mL: #2mL per 28 days.**
- **150mg/mL: #4mL per 28 days.)**

If no, continue to #6.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

6. Is the patient 18 years of age or older **AND** meets the following criterion?
   - The patient had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Otezla (apremilast)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Sotyktu (deucravacitinib)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the following strengths:**
   - **150mg/mL: #1mL per 28 days.**
   - **300mg/2mL: #2mL per 28 days.**
   - **125mg/5mL: #15mL per 28 days.**

   (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
   - **150mg/mL: #4mL per 28 days.**
   - **300mg/2mL: #8mL per 28 days.**
   - **125mg/5mL: #1 fill count [NOTE: Enter a Min Day Supply of 28 days].)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient is 12 to 17 years of age
   - The patient is 18 years of age or older AND had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the following strengths:**
   - **75mg/0.5mL: #0.5mL per 28 days.**
   - **150mg/mL: #1mL per 28 days.**
   - **300mg/2mL: #2mL per 28 days.**
   - **125mg/5mL: #15mL per 28 days.**

   (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
   - **75mg/0.5mL: #2mL per 28 days.**
   - **150mg/mL: #4mL per 28 days.**
   - **125mg/5mL: #1 fill count [NOTE: Enter a Min Day Supply of 28 days].)**

   If no, do not approve.
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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Cimzia (certolizumab)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Cimzia])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, continue to #10.
   If no, continue to #11.

10. Does the patient have **ONE** of the following objective signs of inflammation?
    - C-reactive protein (CRP) levels above the upper limit of normal
    - Sacroiliitis on magnetic resonance imaging (MRI)

    If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the following strengths:**
    - **150mg/mL: #1mL per 28 days.**
    - **125mg/5mL: #15mL per 28 days.**

    (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
    - **150mg/mL: #4mL per 28 days.**
    - **125mg/5mL: #1 fill count [NOTE: Enter a Min Day Supply of 28 days].)**

    If no, do not approve.
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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of enthesitis-related arthritis (ERA) (ICD-10 M08.80) and meet **ALL** of the following criteria?
    - The patient is 4 years of age or older
    - Therapy is prescribed by or in consultation with a rheumatologist
    - Cosentyx will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of ERA
    - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam), sulfasalazine, or methotrexate

    If yes, **approve for 6 months by GPID or GPI-14 for all formulations of the following strengths:**
    - **75mg/0.5mL: #0.5mL per 28 days.**
    - **150mg/mL: #1mL per 28 days.**

    (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
    - **75mg/0.5mL: #2mL per 28 days.**
    - **150mg/mL: #4mL per 28 days.)**

    If no, continue to #12.

12. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
    - Therapy is prescribed by or in consultation with a dermatologist
    - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS
    - The patient had a trial of or contraindication to ONE clinical standard of care therapy: topical therapy (e.g., clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or an oral antibiotic (e.g., tetracycline, dapsone)

    If yes, continue to #13.
    If no, do not approve.
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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

13. Does the patient meet **ONE** of the following criteria?
- The patient is 12 to 17 years of age AND had a trial of or contraindication to the following preferred agent: adalimumab-ryvk/adalimumab-aaty
- The patient is 18 years of age or older AND had a trial of or contraindication to ONE of the following preferred agents:
  - Bimzelx (bimekizumab-bkzx)
  - Adalimumab-ryvk/adalimumab-aaty

  [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

  If yes, **approve for 4 months by GPID or GPI-14 for all formulations of the following strengths:**
  - **150mg/mL: #1mL per 28 days.**
  - **300mg/2mL: #4mL per 28 days.**

  (Please enter a 1 month approval by GPID or GPI-14 for all formulations of the following strengths:
  - **150mg/mL: #4mL per 28 days.**
  - **300mg/2mL: #8mL per 28 days.)**

  If no, do not approve.
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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   5. Enthesitis-related arthritis (ERA: a type of joint condition)
   6. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

B. If you have moderate to severe plaque psoriasis, approval also requires:
   1. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   2. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, face, or scalp
   3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
    a. You are 6 to 11 years of age AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast)
    b. You are 12 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast), Icotyde (icotrokinra)
    c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications:
        i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
        ii. Tremfya (guselkumab)
        iii. Skyrizi (risankizumab-rzaa)
        iv. Enbrel (etanercept)
        v. Otezla (apremilast)
        vi. Taltz (ixekizumab)
        vii. Sotyktu (deucravacitinib)
        viii. Bimzelx (bimekizumab-bkzx)
        ix. Adalimumab-ryvk/adalimumab-aaty
        x. Icotyde (icotrokinra)

C. If you have psoriatic arthritis, approval also requires:

1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Otezla (apremilast)
      iii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      iv. Tremfya (guselkumab)
      v. Skyrizi (risankizumab-rzaa)
      vi. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      iii. Otezla (apremilast)
      iv. Tremfya (guselkumab)
      v. Skyrizi (risankizumab-rzaa)
      vi. Taltz (ixekizumab)
      vii. Bimzelx (bimekizumab-bkzx)
      viii. Sotyktu (deucravacitinib)
      ix. Adalimumab-ryvk/adalimumab-aaty
      x. Xeljanz IR/XR (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      xi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:

1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
4. You meet ONE of the following:
   a. You are 12 to 17 years of age
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Taltz (ixekizumab)
      iii. Bimzelx (bimekizumab-bkzx)
      iv. Adalimumab-ryvk/adalimumab-aaty
      v. Xeljanz IR/XR (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

E. If you have non-radiographic axial spondyloarthritis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
5. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cimzia (certolizumab)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Cimzia])
6. You have ONE of the following signs of inflammation:
   a. C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
   b. Sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

F. If you have enthesitis-related arthritis, approval also requires:
1. You are 4 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of enthesitis-related arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam), sulfasalazine, or methotrexate

G. If you have moderate to severe hidradenitis suppurativa, approval also requires:
1. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)
3. You have tried or have a contraindication to (harmful for you to use) ONE clinical standard of care therapy: topical therapy (such as clindamycin, resorcinol, chlorhexidine, zinc pyrithione, benzoyl peroxide) or an oral antibiotic (such as tetracycline, dapsone)
4. You meet ONE of the following:
   a. You are 12 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the following preferred medication: adalimumab-ryvk/adalimumab- aaty
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Bimzelx (bimekizumab-bkzx)
      ii. Adalimumab-ryvk/adalimumab-aaty

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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SECUKINUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more while on therapy
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #3.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 6 to 11 years of age AND had a trial of or contraindication to FOUR of the following preferred agents: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast)
   - The patient is 12 to 17 years of age AND had a trial of or contraindication to FOUR of the following preferred agents: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast), Icotyde (icotrokinra)
   - The patient is 18 years of age or older AND had a trial of or contraindication to FOUR of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Enbrel (etanercept)
     - Otezla (apremilast)
     - Taltz (ixekizumab)
     - Sotyktu (deucravacitinib)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Icotyde (icotrokinra)

     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
     - **75mg/0.5mL: #0.5mL per 28 days.**
     - **150mg/mL: #1mL per 28 days.**
     - **300mg/2mL: #2mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?

- The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
- Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, continue to #4.
If no, continue to #5.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 5 years of age AND had a trial of or contraindication to ONE of the following preferred agents: Enbrel (etanercept), Xeljanz IR (tofacitinib IR), Rinvoq (upadacitinib)
     [**NOTE**: Xeljanz and Rinvoq require additional criteria of inadequate response or intolerance to a TNF blocker (e.g., Enbrel)]
   - The patient is 6 to 17 years of age AND had a trial of or contraindication to THREE of the following preferred agents:
     - o Enbrel (etanercept)
     - o Otezla (apremilast)
     - o Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - o Tremfya (guselkumab)
     - o Skyrizi (risankizumab-rzaa)
     - o Xeljanz IR (tofacitinib IR)
     - o Rinvoq (upadacitinib)

     [**NOTE**: Xeljanz and Rinvoq require additional criteria of inadequate response or intolerance to a TNF blocker (e.g., Enbrel)]
   - The patient is 18 years of age or older AND had a trial of or contraindication to THREE of the following preferred agents:
     - o Enbrel (etanercept)
     - o Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - o Otezla (apremilast)
     - o Tremfya (guselkumab)
     - o Skyrizi (risankizumab-rzaa)
     - o Taltz (ixekizumab)
     - o Bimzelx (bimekizumab-bkzx)
     - o Sotyktu (deucravacitinib)
     - o Adalimumab-ryvk/adalimumab-aaty
     - o Xeljanz (tofacitinib IR or XR)
     - o Rinvoq (upadacitinib)

     [**NOTE**: Xeljanz and Rinvoq require additional criteria of inadequate response or intolerance to a TNF blocker (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel)]
     [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
     - **75mg/0.5mL: #0.5mL per 28 days.**
     - **150mg/mL: #1mL per 28 days.**
     - **300mg/2mL: #2mL per 28 days.**
     - **125mg/5mL: #15mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient is 12 to 17 years of age
   - The patient is 18 years of age or older AND had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
   - **75mg/0.5mL: #0.5mL per 28 days.**
   - **150mg/mL: #1mL per 28 days.**
   - **300mg/2mL: #2mL per 28 days.**
   - **125mg/5mL: #15mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of nr-axSpA
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - o Cimzia (certolizumab)
     - o Taltz (ixekizumab)
     - o Bimzelx (bimekizumab-bkzx)
     - o Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Cimzia])

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
     - **150mg/mL: #1mL per 28 days.**
     - **125mg/5mL: #15mL per 28 days.**

     If no, continue to #8.

8. Does the patient have a diagnosis of enthesitis-related arthritis (ERA) (ICD-10 M08.80) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion
   - Cosentyx will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of ERA

     If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
     - **75mg/0.5mL: #0.5mL per 28 days.**
     - **150mg/mL: #1mL per 28 days.**

     If no, continue to #9.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) (ICD-10 L73.2) and meet **ALL** of the following criteria?
   - The patient has shown improvement in HS symptoms
   - Cosentyx will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of HS

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

10. Does the patient meet **ONE** of the following criteria?
    - The patient is 12 to 17 years of age AND had a trial of or contraindication to the following preferred agent: adalimumab-ryvk/adalimumab-aaty
    - The patient is 18 years of age or older AND had a trial of or contraindication to ONE of the following preferred agents:
      - Bimzelx (bimekizumab-bkzx)
      - Adalimumab-ryvk/adalimumab-aaty

    [**NOTE**: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 12 months by GPID or GPI-14 for all formulations of the following strengths:**
    - **150mg/mL: #1mL per 28 days.**
    - **300mg/2mL: #4mL per 28 days.**

    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   5. Enthesitis-related arthritis (ERA: a type of joint condition)
   6. Moderate to severe hidradenitis suppurativa (HS: a type of skin condition)

B. If you have moderate to severe plaque psoriasis, renewal also requires:
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50 percent or more while on therapy
   2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   3. You meet ONE of the following:
      a. You are 6 to 11 years of age AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast)
      b. You are 12 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications: Enbrel (etanercept), Skyrizi (risankizumab-rzaa), Taltz (ixekizumab), Tremfya (guselkumab), Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba), Otezla (apremilast), Icotyde (icotrokinra)
      c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) FOUR of the following preferred medications:
         i. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
         ii. Tremfya (guselkumab)
         iii. Skyrizi (risankizumab-rzaa)
         iv. Enbrel (etanercept)
         v. Otezla (apremilast)
         vi. Taltz (ixekizumab)
         vii. Sotyktu (deucravacitinib)
         viii. Bimzelx (bimekizumab-bkzx)
         ix. Adalimumab-ryvk/adalimumab-aaty
         x. Icotyde (icotrokinra)

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      iii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   b. You are 6 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Otezla (apremilast)
      iii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      iv. Tremfya (guselkumab)
      v. Skyrizi (risankizumab-rzaa)
      vi. Xeljanz IR (tofacitinib immediate-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
      vii. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   c. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      iii. Otezla (apremilast)
      iv. Tremfya (guselkumab)
      v. Skyrizi (risankizumab-rzaa)
      vi. Taltz (ixekizumab)
      vii. Bimzelx (bimekizumab-bkzx)
      viii. Sotyktu (deucravacitinib)
      ix. Adalimumab-ryvk/adalimumab-aaty
      x. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      xi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, renewal also requires:
1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
3. You meet ONE of the following:
   a. You are 12 to 17 years of age
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      i. Enbrel (etanercept)
      ii. Taltz (ixekizumab)
      iii. Bimzelx (bimekizumab-bkzx)
      iv. Adalimumab-ryvk/adalimumab-aaty
      v. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      vi. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

E. If you have non-radiographic axial spondyloarthritis, renewal also requires:
1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Cimzia (certolizumab)
   b. Taltz (ixekizumab)
   c. Bimzelx (bimekizumab-bkzx)
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor

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necrosis factor [TNF] blocker [such as Cimzia])

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SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

F. If you have enthesitis-related arthritis, renewal also requires:
1. You have experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of enthesitis-related arthritis (a type of joint condition)

G. If you have moderate to severe hidradenitis suppurativa, renewal also requires:
1. You have shown improvement in your hidradenitis suppurativa symptoms
2. You will NOT use Cosentyx concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of hidradenitis suppurativa (a type of skin condition)
3. You meet ONE of the following:
   a. You are 12 to 17 years of age AND have tried or have a contraindication to (harmful for you to use) the following preferred medication: adalimumab-ryvk/adalimumab- aaty
   b. You are 18 years of age or older AND have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      i. Bimzelx (bimekizumab-bkzx)
      ii. Adalimumab-ryvk/adalimumab-aaty

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cosentyx.

REFERENCES

Cosentyx [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2026.

Created: 02/15
Effective: 07/15/26 Client Approval: 07/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELADELPAR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELADELPAR LYSINE	LIVDELZI	49816		GPI-10 (5278007050)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC), including cholestatic pruritus, as confirmed by at least **TWO** of the following criteria?
   - The patient has an elevated alkaline phosphatase (ALP) level
   - The patient has the presence of antimitochondrial antibodies (AMA) OR other PBC-specific autoantibodies, including sp100 or gp210, if AMA is negative
   - The patient has histologic evidence (obtained by liver biopsy) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist or hepatologist
   - The patient does NOT have decompensated cirrhosis (Child-Pugh B or C)
   - Livdelzi will NOT be used concurrently with any other second-line PBC treatment (Iqirvo [elafibranor]) or Lynavoy (linerixibat)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - Livdelzi will be used as monotherapy in a patient who is unable to tolerate ursodiol (ursodeoxycholic acid)
   - Livdelzi will be used in combination with ursodiol (ursodeoxycholic acid) in a patient who had an inadequate response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SELADELPAR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT:

Our guideline named **SELADELPAR (Livdelzi)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct), including cholestatic pruritus (itching caused by liver disease), as confirmed by TWO of the following:
   1. You have an elevated (high) alkaline phosphatase (ALP) level (a type of lab test)
   2. You have the presence of antimitochondrial antibodies (AMA: indicator of the body attacking its own cells) or other PBC-specific autoantibodies (indicator of the body attacking its own cells), including sp100 or gp210, if AMA is negative
   3. You have histologic evidence (lab data obtained by liver biopsy [removal of cells or tissue from the liver for examination]) of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (symptoms of liver disease)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions) or hepatologist (a type of liver doctor)
D. You do NOT have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (Child-Pugh B or C: a score that evaluates the severity of liver damage)
E. You will NOT use Livdelzi concurrently (at the same time) with any other second-line therapy for primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct) (Iqirvo [elafibranor]) or Lynavoy (linerixibat)
F. You meet ONE of the following:
   1. Livdelzi will be used as monotherapy (one medication treatment) if you are unable to tolerate ursodiol (ursodeoxycholic acid)
   2. Livdelzi will be used in combination (together) with ursodiol (ursodeoxycholic acid) if you had an inadequate (poor) response to at least 1 year of treatment with ursodiol (ursodeoxycholic acid) monotherapy (one medication treatment)

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SELADELPAR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis (PBC), including cholestatic pruritus, **AND** meet the following criterion?
   - Livdelzi will NOT be used concurrently with any other second-line PBC treatment (Iqirvo [elafibranor]) or Lynavoy (linerixibat)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has an alkaline phosphatase (ALP) level that is less than 1.67 times the upper limit of normal AND has decreased by at least 15 percent from baseline while on treatment with Livdelzi
   - The patient has PBC-related cholestatic pruritus AND has shown a clinical response, defined as improvement in pruritus symptoms

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **SELADELPAR (Livdelzi)** requires the following rule(s) be met for renewal:
   A. You have primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct) including cholestatic pruritus (itching caused by liver disease)
   B. You will NOT use Livdelzi concurrently (at the same time) with any other second-line therapy for primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct) (Iqirvo [elafibranor]) or Lynavoy (linerixibat)
   C. You meet ONE of the following:
      1. You have an alkaline phosphatase (ALP) level (a type of lab test) that is less than 1.67 times the upper limit of normal AND which has decreased by at least 15 percent from baseline (before treatment) while on treatment with Livdelzi
      2. You have cholestatic pruritus (itching caused by liver disease) associated with primary biliary cholangitis (PBC: a type of immune system disorder that destroys the bile duct) AND have shown a clinical response, defined as improvement in pruritus (itching) symptoms

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SELADELPAR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Livdelzi.

REFERENCES

Livdelzi [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; January 2026.

Created: 08/24
Effective: 07/04/26 Client Approval: 07/26 DMC Approval: 06/30/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELEXIPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELEXIPAG	UPTRAVI	42922		GPI-10 (4012007000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 2 to 17 years of age
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than or equal to 3 Wood units (WU)

   If yes, **approve all strengths of the tablet formulation for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Uptravi 200-800mcg Titration Pack: #200 per 28 days for 1 fill.**
   - **100mcg tablet: #16 per day.**
   - **150mcg tablet: #10 per day.**
   - **200mcg tablet: #8 per day.**
   - **400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg tablet: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or

   pulmonologist If yes, continue to #4.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SELEXIPAG

INITIAL CRITERIA (CONTINUED)

4. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 as follows (enter first and second approvals):**
   - **FIRST APPROVAL: Approve Uptravi 200-800mcg Titration Pack with a quantity limit of #200 per 28 days for 1 fill.**
   - **SECOND APPROVAL: Approve all strengths as follows:**
     - **200mcg tablet: #8 per day.**
     - **400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg tablet: #2 per day.**
     - **1,800mcg vial: #2 per day.**

   (NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You are 2 years of age or older
   C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   D. You meet ONE of the following:
      1. You are 2 to 17 years of age AND meet the following criterion:
         a. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
            i. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
            ii. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
            iii. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
      2. You are 18 years of age or older AND meet the following criterion:
         a. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
            i. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
            ii. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
            iii. Pulmonary vascular resistance (PVR) greater than 2 Wood units

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SELEXIPAG

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, continue to #2.

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 2 to 17 years of age?

   If yes, **approve all strengths of the tablet formulation for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **100mcg tablet: #16 per day.**
   - **150mcg tablet: #10 per day.**
   - **200mcg tablet: #8 per day.**
   - **400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg tablet: #2 per day.**

   If no, continue to #3.

3. Is the patient 18 years of age or older?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **200mcg tablet: #8 per day.**
   - **400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg tablet: #2 per day.**
   - **1,800mcg vial: #2 per day.**

   (NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

   If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You are 2 years of age or older

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SELEXIPAG

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Uptravi.

REFERENCES

Uptravi [Prescribing Information]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; May 2026.

Created: 01/16
Effective: 08/08/26 DMC Approval: 08/04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELINEXOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELINEXOR	XPOVIO	45854		GPI-10 (2156006000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or

     older If yes, continue to #2.

     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Xpovio be used in combination with bortezomib (Velcade) and dexamethasone **AND** the patient meets the following criterion?
   - The patient has received at least one prior therapy

     If yes, **approve the requested GPID or GPI-14 for 12 months as follows:**
     - **40 mg once weekly dose (GPID 49534/ GPI-14 2156006000B760): #4 per 28 days.**
     - **40 mg once weekly dose (GPID 48265/ GPI-14 2156006000B708): #16 per 28 days. (NOTE: Approve both of the 40 mg once weekly dose above.)**
     - **60 mg once weekly dose (GPID 49537/ GPI-14 2156006000B780): #4 per 28 days.**
     - **80 mg once weekly dose (GPID 58636/ GPI-14 2156006000B785): #4 per 28 days.**
     - **80 mg once weekly dose (GPID 49538/ GPI-14 2156006000B770): #8 per 28 days. (NOTE: Approve both of the 80 mg once weekly dose above.)**
     - **100 mg once weekly dose (GPID 49539/ GPI-14 2156006000B775): #8 per 28 days.**

     If no, continue to #3.

3. Has the patient's cancer relapsed or is refractory (RRMM) and the patient meets **ALL** of the following criteria?
   - Xpovio will be used in combination with dexamethasone
   - The patient has received at least four prior therapies for the treatment of

     RRMM If yes, continue to #4.

     If no, do not approve.
     DENIAL TEXT: See the denial text at the end of the guideline.

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SELINEXOR

GUIDELINES FOR USE (CONTINUED)

4. Is the patient's disease refractory to **ALL** of the following?
   - Two proteasome inhibitors (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
   - Two immunomodulatory agents (e.g., lenalidomide [Revlimid], pomalidomide [Pomalyst])
   - One anti-CD38 monoclonal antibody (e.g., daratumumab [Darzalex])

   If yes, **approve the requested GPID or GPI-14 for 12 months as follows:**
   - **60 mg once weekly dose (GPID 49537/ GPI-14 2156006000B780): #4 per 28 days.**
   - **80 mg once weekly dose (GPID 58636/ GPI-14 2156006000B785): #4 per 28 days.**
   - **80 mg once weekly dose (GPID 49538/ GPI-14 2156006000B770): #8 per 28 days. (NOTE: Approve both of the 80 mg once weekly dose above.)**
   - **100 mg once weekly dose (GPID 49539/ GPI-14 2156006000B775): #8 per 28 days.**
   - **80 mg twice weekly (160 mg total per week) dose (GPID 46634/ GPI-14 2156006000B720): #32 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELINEXOR (Xpovio)** requires the following rule(s) be met for approval:
   A. You have multiple myeloma (MM: a type of blood cancer)
   B. You are 18 years of age or older
   C. You meet ONE of the following:
      1. Xpovio will be used in combination with bortezomib (Velcade) and dexamethasone; and you have received at least ONE prior therapy
      2. You have relapsed or refractory multiple myeloma (RRMM: a type of blood cancer that has returned or did not respond to treatment); Xpovio will be used in combination with dexamethasone; you have received at least four prior therapies for the treatment of RRMM; AND your disease is refractory (non-responsive) to ALL of the following:
         a. Two proteasome inhibitors (such as bortezomib [Velcade], carfilzomib [Kyprolis])
         b. Two immunomodulatory agents (such as lenalidomide [Revlimid], pomalidomide [Pomalyst])
         c. One anti-CD38 monoclonal antibody (such as daratumumab [Darzalex])

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xpovio.

REFERENCES
Xpovio [Prescribing Information]. Newton, MA: Karyopharm Therapeutics Inc.; April 2026.

Created: 07/19
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 07/26

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SELPERCATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELPERCATINIB	RETEVMO	46525		GPI-10 (2153577900)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a *RET* (rearranged during transfection) gene fusion, as detected by an FDA-approved test

   If yes, **approve all formulations and strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **40mg capsule: #3 per day.**
   - **40mg tablet: #4 per day.**
   - **80mg, 120mg, 160mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic medullary thyroid cancer (MTC) (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's cancer has a *RET* (rearranged during transfection)-mutation, as detected by an FDA-approved test
   - The patient requires systemic therapy

   If yes, **approve all formulations and strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **40mg capsule: #3 per day.**
   - **40mg tablet: #4 per day.**
   - **80mg, 120mg, 160mg: #2 per day.**

   If no, continue to #3.

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SELPERCATINIB

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of advanced or metastatic thyroid cancer (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's cancer has a *RET* (rearranged during transfection) gene fusion, as detected by an FDA-approved test
   - The patient requires systemic therapy
   - The cancer is refractory to radioactive iodine therapy (if radioactive iodine is appropriate)

   If yes, **approve all formulations and strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **40mg capsule: #3 per day.**
   - **40mg tablet: #4 per day.**
   - **80mg, 120mg, 160mg: #2 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic solid tumors and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient's tumor has a *RET* (rearranged during transfection) gene fusion, as detected by an FDA-approved test
   - The patient's tumor has progressed on or following prior systemic treatment OR the patient has no satisfactory alternative treatment options

   If yes, **approve all formulations and strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **40mg capsule: #3 per day.**
   - **40mg tablet: #4 per day.**
   - **80mg, 120mg, 160mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SELPERCATINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SELPERCATINIB (Retevmo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic non-small cell lung cancer (a type of lung cancer that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)
   2. Advanced or metastatic medullary thyroid cancer (a type of thyroid cancer that has progressed or has spread to other parts of the body)
   3. Advanced or metastatic thyroid cancer (thyroid cancer that has progressed or has spread to other parts of the body)
   4. Locally advanced or metastatic solid tumors (abnormal mass that has spread to nearby tissue or lymph nodes, or has spread to other parts of the body)

B. If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer has a rearranged during transfection (*RET*) gene fusion (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

C. If you have advanced or metastatic medullary thyroid cancer, approval also requires:
   1. You are 2 years of age or older
   2. Your cancer has a rearranged during transfection (*RET*) mutation (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   3. You require systemic therapy (treatment that targets the entire body)

D. If you have advanced or metastatic thyroid cancer, approval also requires:
   1. You are 2 years of age or older
   2. Your cancer has a rearranged during transfection (*RET*) gene fusion (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   3. You require systemic therapy (treatment that targets the entire body)
   4. Your cancer is refractory (has not responded) to radioactive iodine therapy, if radioactive iodine is appropriate

E. If you have a locally advanced or metastatic solid tumors, approval also requires:
   1. You are 2 years of age or older
   2. Your tumor has a rearranged during transfection (*RET*) gene fusion (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test
   3. Your tumor has progressed (worsened) on or following prior systemic treatment (treatment that targets the entire body) OR you have no alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SELPERCATINIB

GUIDELINES FOR USE (CONTINUED)

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SELPERCATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Retevmo.

REFERENCES

Retevmo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; December 2025.

Created: 07/20
Effective: 12/15/25 Client Approval: 12/25 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SELUMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELUMETINIB SULFATE	KOSELUGO	46451		GPI-10 (2153356550)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurofibromatosis type 1 (NF1) (ICD-10 Q85.01) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has symptomatic, inoperable plexiform neurofibromas (PN)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **10mg: #10 per day.**
   - **25mg: #4 per day.**
   - **5mg: #20 per day.**
   - **7.5mg: #13 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SELUMETINIB (Koselugo)** requires the following rule(s) be met for approval:
   A. You have neurofibromatosis type 1 (NF1: a type of skin and nervous system disorder)
   B. You are 1 year of age or older
   C. You have symptomatic, inoperable (cannot be treated by surgery) plexiform neurofibromas (PN: tumors that grow along the nerves)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Koselugo.

REFERENCES

Koselugo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2025.

Created: 07/20
Effective: 12/15/25 Client Approval: 12/25 P&T Approval: 01/26

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SEMAGLUTIDE - WEGOVY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEMAGLUTIDE	WEGOVY	44675		GPI-10 (6125207000)	BRAND = WEGOVY

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request to reduce the risk of major adverse cardiovascular events (MACE) (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke)?

   If yes, continue to #2.
   If no, continue to #6.

2. Is the patient overweight as defined by **ONE** of the following criteria?
   - The patient has a body mass index (BMI) of at least 27 kg/m(2)
   - The patient is Asian and has a BMI of at least 25 kg/m(2)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Wegovy will be used in combination with a reduced calorie diet and increased physical activity
   - Wegovy will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (e.g., Zepbound [tirzepatide], Mounjaro [tirzepatide])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have established cardiovascular disease as evidenced by **ONE** of the following?
   - Prior myocardial infarction (MI) (ICD-10 Z86.74, I25.2)
   - Prior stroke (ischemic or hemorrhagic stroke) (ICD-10 Z86.73, Group I69.3)
   - Carotid artery stenosis of at least 50 percent (ICD-10 Group I65.2)
   - Symptomatic peripheral arterial disease (PAD) (ICD-10 I73.9), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SEMAGLUTIDE - WEGOVY

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a history of and will continue on, or has a contraindication to, **ALL** of the following standard treatments for the secondary prevention of MACE?
   - An antiplatelet medication (e.g., aspirin, clopidogrel, ticagrelor, aspirin-dipyridamole)
     NOTE: This does NOT apply to patients with a history of a hemorrhagic stroke.
   - A HMG-CoA reductase inhibitor (statins) (e.g., atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
   - A blood pressure medication (e.g., angiotensin-converting enzyme [ACE] inhibitors [e.g., lisinopril], angiotensin II receptor blockers [ARBs] [e.g., losartan], beta blockers [e.g., propranolol])

     If yes, **approve all strengths and formulations for 12 months by GPID or GPI-14.**
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient have a diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH)/non-alcoholic steatohepatitis (NASH) (ICD-10 K75.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hepatologist, gastroenterologist, or endocrinologist
   - The patient is enrolled in or has already completed a lifestyle intervention (e.g., dietary, exercise, psychology)
   - Wegovy will NOT be used concurrently with Rezdiffra (resmetirom), another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]), or a GLP-1/GIP receptor agonist (e.g., Zepbound [tirzepatide], Mounjaro [tirzepatide])
   - The patient has a biopsy or non-invasive test (e.g., elastography, ELF testing) that was obtained in the past 12 months demonstrating liver fibrosis stage 2 or 3

     If yes, **approve all strengths of the pen for 72 weeks by GPID or GPI-14.**
     If no, continue to #7.

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SEMAGLUTIDE - WEGOVY

INITIAL CRITERIA (CONTINUED)

7. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is weight loss or weight management a covered benefit?
   (**NOTE:** If weight loss/weight management is NOT a covered benefit - Denied claim would have this POS message - '*Benefit exclusion if only indicated for weight loss.')*

   If yes, continue to #9.
   If no, do not approve.
   Change PA type to EX (excluded) and dismiss using the Dismissed letter template.

9. Does the patient meet **ALL** of the following criteria?
   - There is physician attestation of active enrollment in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
   - Wegovy will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (e.g., Zepbound [tirzepatide], Mounjaro [tirzepatide])

   If yes, continue to #10.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

10. Is the patient 18 years of age or older and meets **ONE** of the following criteria prior to initiating weight loss therapy?
    - The patient has a body mass index (BMI) of at least 30 kg/m(2)
    - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
    - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)
    - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non- alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)

    If yes, **approve all strengths and formulations for 29 weeks by GPID or GPI-14.**
    If no, continue to #11.

11. Is the patient 12 to 17 years of age **AND** meets the following criterion?
    - The patient has an initial BMI at the 95th percentile or greater standardized for age and sex (see table below)

BMI Cut-offs for Obesity by Age and Sex

Age (in years)	Male	Female
	95th Percentile BMI Value	95th Percentile BMI Value
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30.0

If yes, **approve all strengths of the pen for 29 weeks by GPID or GPI-14.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for approval:

A. The request is for ONE of the following:
   1. To reduce the risk of major adverse cardiovascular events (MACE: cardiovascular death, non-fatal myocardial infarction [heart attack], or non-fatal stroke [a type of brain damage])
   2. Noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)/non-alcoholic steatohepatitis (NASH: a type of liver disease)
   3. Weight loss or weight management

B. If you will use Wegovy to reduce the risk of major adverse cardiovascular events, approval also requires:
   1. You are 18 years of age or older
   2. You are overweight as defined by ONE of the following:
      a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2)
      b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2)
   3. Wegovy will be used in combination with a reduced calorie diet and increased physical activity
   4. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
   5. You have established cardiovascular disease as evidenced by ONE of the following:
      a. Prior myocardial infarction (heart attack)
      b. Prior stroke (ischemic [stroke caused by blood clot] or hemorrhagic [stroke caused by broken blood vessels in the brain])
      c. Carotid artery stenosis of at least 50 percent (the blood vessel that transports blood to the brain is blocked)
      d. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication (pain caused by too little blood flow) with ankle-brachial index (ABI: a type of test to check blood flow) less than 0.85 (at rest), peripheral arterial revascularization procedure (surgery to restore blood flow in blocked arteries/veins), or amputation due to atherosclerotic disease (buildup of fat)

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INITIAL CRITERIA (CONTINUED)

6. You have a history of and will continue to use, or you have a contraindication to (harmful for you to use), ALL of the following standard treatments for the secondary prevention (reduce the risk) of a major adverse cardiovascular event:
   a. An antiplatelet medication (such as aspirin, clopidogrel, ticagrelor, aspirin-dipyridamole), unless you have a history of a hemorrhagic stroke (bleeding in the brain caused by broken blood vessels)
   b. A HMG-CoA reductase inhibitor (statins) (such as atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
   c. A blood pressure medication (such as angiotensin-converting enzyme inhibitors [ACEi such as lisinopril], angiotensin II receptor blockers [ARBs such as losartan], beta blockers [such as propranolol])

C. If you will use Wegovy for noncirrhotic metabolic dysfunction-associated steatohepatitis/non-alcoholic steatohepatitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor), gastroenterologist (doctor who treats digestive conditions), or endocrinologist (a type of hormone doctor)
3. You are enrolled in or have already completed a lifestyle intervention (such as dietary, exercise, psychology)
4. You will NOT use Wegovy concurrently (at the same time) with Rezdiffra (resmetirom), another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]), or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
5. You have had a biopsy (removal of cells or tissue from the body for examination) or non- invasive test (such as elastography [type of imaging test], Enhanced Liver Fibrosis [ELF] testing [a type of blood test]) in the past 12 months which demonstrates liver fibrosis stage 2 or 3 (scoring system to measure liver damage)

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INITIAL CRITERIA (CONTINUED)

D. If you will use Wegovy for weight loss or weight management, approval also requires:

1. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
2. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
3. You meet ONE of the following:
   a. You are 18 years of age or older and meet ONE of the following before starting weight loss therapy:
      i. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
      ii. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
      iii. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
      iv. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
   b. You are 12 to 17 years of age and meet the following:
      i. You have an initial body mass index (BMI: a tool for evaluating body fat) in the 95th percentile or greater standardized for your age and sex

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SEMAGLUTIDE - WEGOVY

RENEWAL CRITERIA

1. Is the request to reduce the risk of cardiovascular death, heart attack, and stroke, and the patient meets **ALL** of the following criteria?
   - The patient has established cardiovascular disease (e.g., prior myocardial infarction (MI) [ICD-10 Z86.74, I25.2], prior stroke [ICD-10 Z86.73, Group I69.3], carotid artery stenosis of at least 50 percent [ICD-10 Group I65.2], symptomatic peripheral arterial disease [PAD] [ICD-10 I73.9])
   - Wegovy will be used in combination with a reduced calorie diet and increased physical activity
   - Wegovy will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (e.g., Zepbound [tirzepatide], Mounjaro [tirzepatide])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a history of and will continue on, or has a contraindication to, **ALL** of the following standard treatments for the secondary prevention of MACE?
   - An antiplatelet medication (e.g., aspirin, clopidogrel, ticagrelor, aspirin-dipyridamole)
     NOTE: This does NOT apply to patients with a history of a hemorrhagic stroke.
   - A HMG-CoA reductase inhibitor (statins) (e.g., atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
   - A blood pressure medication (e.g., angiotensin-converting enzyme [ACE] inhibitors [e.g., lisinopril], angiotensin II receptor blockers [ARBs] [e.g., losartan], beta blockers [e.g., propranolol])

   If yes, **approve all strengths and formulations for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH)/non-alcoholic steatohepatitis (NASH) (ICD-10 K75.81) and meet **ALL** of the following criteria?
   - The patient has a disease stability or improvement from baseline
   - Wegovy will NOT be used concurrently with Rezdiffra (resmetirom), another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]), or a GLP-1/GIP receptor agonist (e.g., Zepbound [tirzepatide], Mounjaro [tirzepatide])
   - The patient had a biopsy or non-invasive test (e.g., elastography, ELF testing) demonstrating liver fibrosis stage 2 or 3

   If yes, **approve all strengths of the pen for 12 months by GPID or GPI-14.**
   If no, continue to #4.

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SEMAGLUTIDE - WEGOVY

RENEWAL CRITERIA (CONTINUED)

4. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Is weight loss or weight management a covered benefit?
   (**NOTE:** If weight loss/weight management is NOT a covered benefit - Denied claim would have this POS message - '*Benefit exclusion if only indicated for weight loss.')*

   If yes, continue to #6.
   If no, do not approve.
   Change PA type to EX (excluded) and dismiss using the Dismissed letter template.

6. Will Wegovy be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (e.g., Zepbound [tirzepatide], Mounjaro [tirzepatide])?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #7.

7. Is the patient 12 to 17 years of age **AND** meets the following criterion?
   - The patient has achieved or maintained at least a 5 percent weight loss of baseline body mass index (BMI)

   If yes, **approve all strengths of the pen for 12 months by GPID or GPI-14.**
   If no, continue to #8.

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RENEWAL CRITERIA (CONTINUED)

8. Is the patient 18 years of age or older and meets **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non- alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

9. Has the patient achieved or maintained at least a 5 percent weight loss of baseline body weight?

   If yes, **approve all strengths and formulations for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SEMAGLUTIDE - WEGOVY

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SEMAGLUTIDE - WEGOVY** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. To reduce the risk of cardiovascular death, heart attack, and stroke (a type of brain damage)
   2. Noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH: a type of liver disease)/non-alcoholic steatohepatitis (NASH: a type of liver disease)
   3. Weight loss or weight management

B. If you will use Wegovy to reduce the risk of cardiovascular death, heart attack, and stroke, renewal also requires:
   1. You have cardiovascular disease (such as prior heart attack, prior stroke, carotid artery stenosis of at least 50 percent [the blood vessel that transports blood to the brain is blocked], symptomatic peripheral arterial disease [PAD])
   2. Wegovy will be used in combination with a reduced calorie diet and increased physical activity
   3. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
   4. You have a history of and will continue to use, or you have a contraindication to (harmful for you to use), ALL of the following standard treatments for the secondary prevention (reduce the risk) of a major adverse cardiovascular event (such as a non-fatal myocardial infarction [heart attack], non-fatal stroke [a type of brain damage]):
      a. An antiplatelet medication (such as aspirin, clopidogrel, ticagrelor, aspirin-dipyridamole), unless you have a history of a hemorrhagic stroke (a type of brain damage caused by broken blood vessels in the brain)
      b. A HMG-CoA reductase inhibitor (statins) (such as atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
      c. A blood pressure medication (such as angiotensin-converting enzyme inhibitors [ACEi such as lisinopril], angiotensin II receptor blockers [ARBs such as losartan], beta blockers [such as propranolol])

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RENEWAL CRITERIA (CONTINUED)

C. If you will use Wegovy for noncirrhotic metabolic dysfunction-associated steatohepatitis/non-alcoholic steatohepatitis, renewal also requires:

1. Your disease is stable or has improved from baseline
2. You will NOT use Wegovy concurrently (at the same time) with Rezdiffra (resmetirom), another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]), or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])
3. You have had a biopsy (removal of cells or tissue from the body for examination) or non- invasive test (such as elastography [type of imaging test], Enhanced Liver Fibrosis [ELF] testing [a type of blood test]) which demonstrates liver fibrosis stage 2 or 3 (scoring system to measure liver damage)

D. If you will use Wegovy for weight loss or weight management, renewal also requires:

1. You will NOT use Wegovy concurrently (at the same time) with another GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release]) or a GLP-1/GIP receptor agonist (a type of medication such as Zepbound [tirzepatide], Mounjaro [tirzepatide])

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RENEWAL CRITERIA (CONTINUED)

2. You meet ONE of the following:
   a. You are 12 to 17 years of age AND have achieved or maintained at least a 5 percent weight loss of baseline body mass index (BMI: a tool for evaluating body fat)
   b. You are 18 years of age or older and meet ALL of the following:
      i. You meet ONE of the following before starting weight loss therapy:
         1. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
         2. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
         3. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
         4. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
      ii. You have achieved or maintained at least a 5 percent weight loss of baseline body weight

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RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Wegovy.

REFERENCES
Wegovy [Prescribing Information]. Plainsboro, NJ: Novo Nordisk, Inc.; May 2026.

Created: 03/24
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 10/25

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SEPIAPTERIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEPIAPTERIN	SEPHIENCE	50760		GPI-10 (3090856800)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of sepiapterin-responsive phenylketonuria (PKU) with hyperphenylalaninemia (HPA) (ICD-10 E70.1) and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a metabolic or genetic disease specialist
   - The patient follows a phenylalanine-restricted diet
   - Sephience will NOT be used concurrently with another agent indicated for the treatment of phenylketonuria (PKU) (e.g., Kuvan [sapropterin], Palynziq [pegvaliase-pqpz])
   - The patient had a trial of or contraindication to the preferred agent: Kuvan (sapropterin)

   If yes, **approve for 6 weeks by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SEPIAPTERIN (Sephience)** requires the following rule(s) be met for approval:
   A. You have sepiapterin-responsive phenylketonuria (PKU: a type of genetic metabolic disorder) with hyperphenylalaninemia (HPA: high levels of a type of amino acid)
   B. You are 1 month of age or older
   C. Therapy is prescribed by or in consultation with a metabolic or genetic disease specialist (a doctor that treats metabolic or gene disorders)
   D. You follow a phenylalanine-restricted diet (a type of diet)
   E. You will NOT use Sephience concurrently (at the same time) with another medication indicated for the treatment of phenylketonuria (PKU) (such as Kuvan [sapropterin], Palynziq [pegvaliase-pqpz])
   F. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kuvan (sapropterin)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SEPIAPTERIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of sepiapterin-responsive phenylketonuria (PKU) with hyperphenylalaninemia (HPA) (ICD-10 E70.1) and meet **ALL** of the following criteria?
   - The patient has experienced a reduction in phenylalanine (Phe) levels by at least 30% compared to baseline or to a level below 360 micromoles/L
   - Sephience will NOT be used concurrently with another agent indicated for the treatment of phenylketonuria (PKU) (e.g., Kuvan [sapropterin], Palynziq [pegvaliase-pqpz])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SEPIAPTERIN (Sephience)** requires the following rule(s) be met for renewal:
   A. You have sepiapterin-responsive phenylketonuria (PKU: a type of genetic metabolic disorder) with hyperphenylalaninemia (HPA: high levels of a type of amino acid)
   B. Your phenylalanine (Phe) levels have decreased by at least 30 percent compared to baseline (before treatment) or to a level below 360 micromoles/L
   C. You will NOT use Sephience concurrently (at the same time) with another medication indicated for the treatment of phenylketonuria (PKU) (such as Kuvan [sapropterin], Palynziq [pegvaliase-pqpz])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sephience.

REFERENCES
Sephience [Prescribing Information]. Warren, NJ: PTC Therapeutics, Inc.; September 2025.

Created: 08/25
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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SETMELANOTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SETMELANOTIDE ACETATE	IMCIVREE	47002		GPI-10 (3090846010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of obesity (ICD-10 E66.8, E66.9) due to Bardet-Biedl syndrome (BBS) (ICD-10 Q87.83) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist, geneticist, or metabolic specialist
   - The patient meets ONE of the following criteria:
     - The patient is 2 to 5 years of age AND has a baseline body mass index (BMI) of at least in the 97th percentile for age, sex, and body weight
     - The patient is 6 to 17 years of age AND has a baseline body weight of at least in the 97th percentile using growth chart assessments
     - The patient is 18 years of age or older AND has a baseline body mass index (BMI) of at least 30 kg/m2

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.** If no, continue to #2.

2. Does the patient have a diagnosis of obesity due to a pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency (ICD-10 E88.82), as determined by an FDA-approved genetic test, and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist, geneticist, or metabolic specialist
   - The patient meets ONE of the following criteria:
     - The patient is 2 to 5 years of age AND has a baseline body mass index (BMI) of at least in the 97th percentile for age and sex
     - The patient is 6 to 17 years of age AND has a baseline body weight of at least in the 95th percentile using growth chart assessments
     - The patient is 18 years of age or older AND has a baseline body mass index (BMI) of at least 30 kg/m2

   If yes, **approve for 16 weeks by HICL or GPI-10 with a quantity limit of #0.3 mL per day.** If no, continue to #3.

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SETMELANOTIDE

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of acquired hypothalamic obesity (HO) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist, geneticist, or metabolic specialist
   - The patient has or had hypothalamic damage or injury (e.g., tumors impacting the hypothalamus [such as craniopharyngioma], surgery or radiation to treat those tumors, other forms of hypothalamic damage [such as brain injury impacting the region])
   - The patient meets ONE of the following criteria:
     - The patient is 4 to 17 years of age AND has a baseline body mass index (BMI) of at least in the 95th percentile for age and sex on growth chart assessments
     - The patient is 18 years of age or older AND has a baseline body mass index (BMI) of at least 30 kg/m2

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.3mL per day.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Obesity (a condition where you have higher than normal body fat) due to Bardet-Biedl syndrome (BBS: a genetic disorder)
      2. Obesity (a condition where you have higher than normal body fat) due to pro-opiomelanocortin (POMC: type of protein), proprotein convertase subtilisin/kexin type 1 (PCSK1: type of protein), or leptin receptor (LEPR: type of protein) deficiency (low level), as determined by a Food and Drug Administration (FDA)-approved genetic test
      3. Acquired hypothalamic obesity (a condition where you have higher than normal body fat due to injury to the hypothalamus [a part of the brain])

   (Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

B. If you have obesity due to Bardet-Biedl syndrome, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (doctor who treats gene disorders), or metabolic specialist (a doctor or health expert who focuses on how the body turns food into energy)
2. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have a baseline (before treatment) body mass index (BMI: a tool for evaluating body fat) of at least in the 97th percentile for age, sex, and body weight
   b. You are 6 to 17 years of age AND have a baseline (before treatment) body weight of at least in the 97th percentile using growth chart assessments
   c. You are 18 years of age or older AND have a baseline (before treatment) body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m2

C. If you have obesity due to pro-opiomelanocortin, proprotein convertase subtilisin/kexin type 1, or leptin receptor deficiency, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (doctor who treats gene disorders), or metabolic specialist (a doctor or health expert who focuses on how the body turns food into energy)
2. You meet ONE of the following:
   a. You are 2 to 5 years of age AND have a baseline (before treatment) body mass index (BMI: a tool for evaluating body fat) of at least in the 97th percentile for age and sex
   b. You are 6 to 17 years of age AND have a baseline (before treatment) body weight of at least in the 95th percentile using growth chart assessments
   c. You are 18 years of age or older AND have a baseline (before treatment) body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m2

D. If you have acquired hypothalamic obesity, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), geneticist (doctor who treats gene disorders), or metabolic specialist (a doctor or health expert who focuses on how the body turns food into energy)
2. You have or had hypothalamic damage or injury (damage or injury to part of the brain such as tumors impacting the hypothalamus [such as craniopharyngioma (a non- cancerous brain tumor)], surgery or radiation to treat those tumors, other forms of hypothalamic damage [such as brain injury impacting the region])
3. You meet ONE of the following:
   a. You are 4 to 17 years of age AND have a baseline (before treatment) body mass index (BMI: a tool for evaluating body fat) of at least in the 95th percentile for age and sex on growth chart assessments
   b. You are 18 years of age or older AND have a baseline (before treatment) body mass index (BMI) of at least 30 kg/m2

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SETMELANOTIDE

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Bardet-Biedl syndrome (BBS) (ICD-10 Q87.83)
   - Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency
   - Acquired hypothalamic obesity (HO)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient is 2 to 17 years of age AND has achieved or maintained at least a 5 percent weight loss of baseline body mass index (BMI)
   - The patient is 18 years of age or older AND has achieved or maintained at least a 5 percent weight loss of baseline body weight

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.3 mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Bardet-Biedl syndrome (BBS: a genetic disorder)
      2. Pro-opiomelanocortin (POMC: type of protein), proprotein convertase subtilisin/kexin type 1 (PCSK1: type of protein), or leptin receptor (LEPR: type of protein) deficiency (low level)
      3. Acquired hypothalamic obesity (HO: a condition where you have higher than normal body fat due to injury to the hypothalamus [a part of the brain])
   B. You meet ONE of the following:
      1. You are 2 to 17 years of age AND have achieved or maintained at least a 5 percent weight loss of baseline (before treatment) body mass index (BMI: a tool for evaluating body fat)
      2. You are 18 years of age or older AND have achieved or maintained at least a 5 percent weight loss of baseline (before treatment) body weight

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SETMELANOTIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imcivree.

REFERENCES

Imcivree [Prescribing Information]. Boston, MA: Rhythm Pharmaceuticals, Inc.; March 2026.

Created: 02/21
Effective: 08/21/26 Client Approval: 08/26 DMC T Approval: 08/11/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SEVABERTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SEVABERTINIB	HYRNUO	51015		GPI-10 (2153305700)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has tumors with HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutations, as detected by an FDA-authorized test

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT:

   Our guideline named **SEVABERTINIB (Hyrnuo)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) (a type of lung cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body)
   B. You are 18 years of age or older
   C. Your tumors have HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutations (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hyrnuo.

REFERENCES

Hyrnuo [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; September 2026.

Created: 12/25
Effective: 09/18/26 Client Approval: 09/26 DMC Approval: 09/22/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIBEPRENLIMAB-SZSI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIBEPRENLIMAB-SZSI	VOYXACT	51027		GPI-10 (5648055000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is at risk for disease progression
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a biopsy
   - The patient has proteinuria of at least 0.5 g/day
   - The patient has an eGFR of at least 30 mL/min/1.73 m(2)
   - The patient has tried an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan) for at least 3 months at a maximum tolerated dose and will continue use, OR has a contraindication to both drug classes
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Vanrafia (atrasentan), Filspari (sparsentan), Fabhalta (iptacopan)

   If yes, **approve for 9 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SIBEPRENLIMAB-SZSI

INITIAL CRITERIA (CONTINUED ON NEXT PAGE)

INITIAL DENIAL TEXT:

Our guideline named **SIBEPRENLIMAB-SZSI (Voyxact)** requires the following rule(s) be met for approval:

A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
B. You are 18 years of age or older
C. You are at risk for disease progression (worsening of disease)
D. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
E. Your diagnosis is confirmed by a biopsy (removal of cells or tissue from the kidney for examination)
F. You have proteinuria (high levels of protein in the urine) of at least 0.5 g/day
G. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
H. You have tried an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan) for at least three months at a maximum tolerated dose and will continue use, OR you have a contraindication to (harmful for you to use) both of these medication classes
I. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Vanrafia (atrasentan), Filspari (sparsentan), Fabhalta (iptacopan)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIBEPRENLIMAB-SZSI

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ONE** of the following criteria?
   - The patient has had a reduction in proteinuria
   - The patient has improved or stable kidney function compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **SIBEPRENLIMAB-SZSI (Voyxact)** requires the following rule(s) be met for renewal:
   A. You have primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
   B. You meet ONE of the following:
      1. You have had a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)
      2. You have improved or stable kidney function compared to baseline (before starting Voyxact)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Voyxact.

REFERENCES
Voyxact [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; November 2025.

Created: 07/26
Effective: 07/01/26 Client Approval: 07/26 DMC Approval: 06/30/26

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SILDENAFIL IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE		28273	GPI-14 (40143060102020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #37.5mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL IV

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 2 Wood units
E. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
F. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL IV

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes**, approve for 12 months by GPID or GPI-14 with a quantity limit of #37.5mL per day.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL IV (Revatio)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio.

REFERENCES

Revatio [Prescribing Information]. New York, NY: Pfizer Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/08
Client Approval: 06/24
P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, LIQREV, SILDENAFIL CITRATE		33186 54078	GPI-14 (40143060101920, 40143060101825)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The request is for Revatio (sildenafil) suspension
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])
   - The patient is unable to swallow pills and has tried crushed sildenafil tablets

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than or equal to 3 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #14.93mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the request for **Revatio** (sildenafil) suspension **AND** the patient meets the following criterion?
   - The patient is unable to swallow pills and has tried crushed sildenafil tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #26.13mL per day.**
   If no, continue to #6.

6. Is the request for **Liqrev** suspension and the patient meets **ALL** of the following criteria?
   - The patient is unable to swallow Revatio (sildenafil) tablets
   - The patient had a trial of the preferred agent: generic sildenafil powder for suspension

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #8.13mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

B. If you are 1 to 17 years of age, approval also requires:

1. You are requesting Revatio (sildenafil) suspension
2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
3. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
4. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
5. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])
6. You are unable to swallow pills AND you have tried crushed sildenafil tablets

C. If you are 18 years of age or older, approval also requires:

1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

(Initial denial text continued on next page)

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SILDENAFIL SUSPENSION

INITIAL CRITERIA (CONTINUED)

5. If you are requesting Revatio (sildenafil) suspension, you are unable to swallow pills AND you have tried crushed sildenafil tablets
6. If you are requesting Liqrev suspension, you are unable to swallow Revatio (sildenafil) tablets AND you have tried the preferred medication: generic sildenafil powder for suspension

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SILDENAFIL SUSPENSION

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 1 to 17 years of age **AND** meets the following criterion?
   - The request is for Revatio (sildenafil) suspension

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #14.93mL per day.**
   If no, continue to #3.

3. Is the patient 18 years of age or older?

   If yes**, approve for 12 months by GPID or GPI-14 for the requested agent with the following quantity limits:**
   - **Revatio (sildenafil): #26.13mL per day.**
   - **Liqrev (sildenafil): #8.13mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SILDENAFIL SUSPENSION

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILDENAFIL SUSPENSION (Revatio, Liqrev)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

B. If you are 1 to 17 years of age, approval also requires:

1. You are requesting Revatio (sildenafil) suspension
2. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
3. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

C. If you are 18 years of age or older, approval also requires:

1. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
2. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio and Liqrev.

REFERENCES

Revatio [Prescribing Information]. New York, NY: Pfizer Inc.; October 2024.
Liqrev [Prescribing Information]. Farmville, NC: CMP Pharma Inc.; April 2023.

Created: 01/08
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILDENAFIL TABLET

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILDENAFIL CITRATE	REVATIO, SILDENAFIL CITRATE		24758	GPI-14 (40143060100320)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than or equal to 3 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SILDENAFIL TABLET

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #12 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   (Initial denial text continued on next page)

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SILDENAFIL TABLET

INITIAL CRITERIA (CONTINUED)

B. If you are 1 to 17 years of age, approval also requires:

1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   c. Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

C. If you are 18 years of age or older, approval also requires:

1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
3. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
4. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL TABLET

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient 1 to 17 years of age?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day.**
   If no, continue to #3.

3. Is the patient 18 years of age or older?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #12 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SILDENAFIL TABLET (Revatio)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You are 1 year of age or older
   C. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   D. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SILDENAFIL TABLET

RENEWAL CRITERIA

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SILDENAFIL TABLET

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revatio.

REFERENCES

Revatio [Prescribing Information]. New York, NY: Pfizer Inc.; January 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24
Created: 01/08
Client Approval: 06/24
P&T Approval: 01/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SILTUXIMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SILTUXIMAB	SYLVANT	41101		GPI-10 (9947308000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multi-centric Castleman's disease (MCD)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient positive for either human immunodeficiency virus (HIV) or human herpesvirus-8 (HHV-8)?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, **approve for 12 months by HICL or GPI-10.**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SILTUXIMAB (Sylvant)** requires the following rule(s) be met for approval:
A. You have multi-centric Castleman's disease (MCD: disease that affects the lymph nodes and related tissues)
B. You are negative for both human immunodeficiency virus (HIV) and human herpes virus-8 (HHV-8)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sylvan.

REFERENCES

Sylvant [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; May 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 6/14
Client Approval: 04/20
P&T Approval: 08/14

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIMVASTATIN 80

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EZETIMIBE/ SIMVASTATIN	VYTORIN		23126	GPI-14 (39994002300350)	
SIMVASTATIN	ZOCOR, SIMVASTATIN		26535	GPI-14 (39400075000360)	

GUIDELINES FOR USE

1. Has the patient been taking the requested medication for at least 12 months?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIMVASTATIN 80 (VYTORIN, ZOCOR)** requires the following rule(s) be met for approval:
   A. You have been taking the medication for at least 12 months

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vytorin and Zocor.

REFERENCES

Vytorin [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2020.
Zocor [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/14/21
Created: 08/11
Client Approval: 05/21
P&T Approval: 08/11

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIMVASTATIN ORAL SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIMVASTATIN	FLOLIPID		41189 41192	GPI-14 (39400075001810, 39400075001820)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?
   - The patient has a contraindication to or is unable to swallow simvastatin oral tablets
   - The patient has dysphagia (ICD-10 Group R13.1), difficulty swallowing tablets, or a feeding tube (e.g., G-tube or J-tube)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient also requesting a zero-dollar cost share exception (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #3.
   If no, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of #5mL per day.**

3. Does the patient meet **ALL** of the following criteria?
   - The patient is between 40 to 75 years old
   - The requested quantity is within the low to moderate intensity daily dosage of 5mg to 40mg
   - The patient is NOT concurrently taking any of the below secondary prevention medications for cardiovascular disease:
     - Aspirin/dipyridamole (Aggrenox)
     - Clopidogrel (Plavix)
     - Dipyridamole
     - Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
     - Prasugrel (Effient)
     - Ticagrelor (Brilinta)
     - Ticlopidine
     - Vorapaxar (Zontivity)

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of #5mL per day at zero copay.**

   If no, **approve the requested medication for 12 months by GPID or GPI-14 with a quantity limit of #5mL per day (DO NOT enter a zero copay).**

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SIMVASTATIN ORAL SUSPENSION

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SIMVASTATIN ORAL SUSPENSION (Flolipid)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow simvastatin oral tablets
   2. You have dysphagia (difficulty swallowing), difficulty swallowing tablets, or a feeding tube (such as a G-tube or J-tube)

B. Requests for zero-dollar cost share also requires the following:
   1. You are between 40 to 75 years old
   2. The requested quantity is within the low to moderate intensity daily dosage of 5mg to 40mg
   3. You are NOT concurrently (at the same time) taking any of the following secondary prevention medications for cardiovascular disease (heart disease):
      a. Aspirin/dipyridamole (Aggrenox)
      b. Clopidogrel (Plavix)
      c. Dipyridamole
      d. Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
      e. Prasugrel (Effient)
      f. Ticagrelor (Brilinta)
      g. Ticlopidine
      h. Vorapaxar (Zontivity)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Flolipid.

This guideline also applies to plans where the pharmacy benefit allows for coverage of Flolipid at zero copay. The override criteria allow patient a zero copay by waiving the applicable cost-sharing to Flolipid, which is included in the MedImpact EHB Zero Dollar Copay List.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIMVASTATIN ORAL SUSPENSION

REFERENCES

Flolipid [Prescribing Information]. Brooksville, FL: Salerno Pharmaceuticals LP; June 2020.

U.S. Preventive Services Task Force [Final Summary]. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication. Updated August 2022. Available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/statin-use-in-adults-preventive-medication. Accessed October 2025.

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs. Accessed October 2025.

Created: 03/18
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIPONIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIPONIMOD	MAYZENT	45670		GPI-10 (6240707020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ANY** of the following contraindications to Mayzent?
   - The patient has a CYP2C9*3/*3 genotype
   - Within the last 6 months, experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
   - A presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, or sick sinus syndrome, unless the patient has a functioning pacemaker

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #3.

3. Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack for 2 mg maintenance dose: #12 tablets (1 pack) per fill.**
   - **Mayzent 2mg: #1 per day.**

   If no, continue to #4.

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SIPONIMOD

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a CYP2C9 *1/*3 or *2/*3 genotype?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **Mayzent 0.25mg starter pack for 1 mg maintenance dose: #7 tablets (1 pack) per fill.**
   - **Mayzent 0.25mg: #4 per day.**
   - **Mayzent 1mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms or disease returns and goes away), or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have a CYP2C9 (type of enzyme) *1/*1, *1/*2, *2/*2, *1/*3, or *2/*3 genotype
   D. You do NOT have any of the following contraindications to (harmful for you to use) Mayzent:
      1. A CYP2C9*3/*3 genotype
      2. Within the last 6 months, experienced a myocardial infarction (heart attack), unstable angina (chest pain), stroke, transient ischemic attack (TIA: short stroke-like attack), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
      3. A presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, OR sick sinus syndrome, unless you have a functioning pacemaker (a small device that is placed [implanted] in your chest to help control your heartbeat)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mayzent.

REFERENCES

Mayzent [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2025.

Created: 04/19
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIROLIMUS PROTEIN-BOUND (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIROLIMUS PROTEIN-BOUND	FYARRO	47680		GPI-10 (2153256020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIROLIMUS PROTEIN-BOUND (Fyarro)** requires the following rule(s) be met for approval:
   A. You have locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa: a type of rare tumor, that cannot be completely removed with surgery and has spread to nearby tissue or lymph nodes, or that has spread to other parts of the body)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fyarro.

REFERENCES

Fyarro [Prescribing Information]. Pacific Palisades, CA: Aadi Bioscience, Inc.; November 2021.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 01/22
Client Approval: 02/22
P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIROLIMUS TOPICAL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SIROLIMUS	HYFTOR		52138	GPI-10 (9078407000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of facial angiofibroma associated with tuberous sclerosis (ICD-10 Q85.1) **AND** meet the following criterion?
   - The patient is 6 years of age or older

   If yes, **approve for 12 weeks by GPID or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for approval:
   A. You have facial angiofibroma (a type of skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)
   B. You are 6 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SIROLIMUS TOPICAL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of facial angiofibroma associated with tuberous sclerosis (ICD-10 Q85.1)?

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SIROLIMUS TOPICAL (Hyftor)** requires the following rule(s) be met for renewal:
   A. You have facial angiofibroma (a type of skin condition) associated with tuberous sclerosis (a rare type of tumor disorder)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hyftor.

REFERENCES

Hyftor [Prescribing Information]. Bethesda, MD: Nobelpharma America, LLC.; March 2022.

Created: 08/22
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 07/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM OXYBATE-LUMRYZ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM OXYBATE	LUMRYZ	12346		GPI-10 (6245006020)	FORM ≠ SOLUTION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cataplexy with narcolepsy (ICD-10 G47.411) and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs)
   - The patient has a SOREMP within 15 minutes of sleep onset
   - The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has an Epworth Sleepiness Scale (ESS) score greater than 10
   - The patient had a trial of the preferred agent: generic sodium oxybate
   - Lumryz will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   - **Lumryz 28-day Starter Pack: #1 per day for 1 fill only.**
   - **4.5gm packet: #1 per day.**
   - **6gm packet: #1 per day.**
   - **7.5gm packet: #1 per day.**
   - **9gm packet: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419) and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has excessive daytime sleepiness (EDS) persisting for at least 3 months
   - The patient has an Epworth Sleepiness Scale (ESS) score of greater than 10
   - The patient had a trial of the preferred agent: generic sodium oxybate
   - Lumryz will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient's diagnosis confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least two early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least one early-onset REM sleep period (SOREMP) AND additionally one early-onset SOREMP (within approximately 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [**Note to Pharmacist:** Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout *a single test* day at 2-hour intervals]
   - The patient has normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   - **Lumryz 28-day Starter Pack: #1 per day for 1 fill only.**
   - **4.5gm packet: #1 per day.**
   - **6gm packet: #1 per day.**
   - **7.5gm packet: #1 per day.**
   - **9gm packet: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE-LUMRYZ** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Cataplexy with narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
   2. Excessive daytime sleepiness (EDS) with narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)

B. If you have cataplexy with narcolepsy, approval also requires:
   1. You are 7 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
   3. You have an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   4. Your narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs: time it takes to enter dream sleep)
      b. You have a sleep-onset rapid eye movement period (SOREMP: time it takes to enter dream sleep) within 15 minutes of sleep onset
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   5. You have tried the preferred medication: generic sodium oxybate
   6. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

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SODIUM OXYBATE-LUMRYZ

INITIAL CRITERIA (CONTINUED)

C. If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:

1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
4. You have excessive daytime sleepiness (EDS) persisting for at least 3 months
5. You have an Epworth Sleepiness Scale (tool to measure your sleepiness) score of greater than 10
6. You have tried the preferred medication: generic sodium oxybate
7. Your diagnosis is confirmed by ONE of the following:
   a. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency of 8 minutes or less AND at least 2 early-onset rapid eye movement (REM) sleep test periods (SOREMPs: time it takes to enter dream sleep)
   b. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing an average sleep latency of 8 minutes or less AND at least one early-onset rapid eye movement (REM) sleep test period (SOREMP: time it takes to enter dream sleep) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night before the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
   c. You have normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have normal levels of a chemical that helps with staying awake)

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SODIUM OXYBATE-LUMRYZ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy (ICD-10 Group G47.41) **AND** meet the following criterion?
   - Lumryz will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25 percent compared to baseline
   - The patient has demonstrated improvement in sleep latency compared to baseline

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **4.5gm packet: #1 per day.**
   - **6gm packet: #1 per day.**
   - **7.5gm packet: #1 per day.**
   - **9gm packet: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM OXYBATE-LUMRYZ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE-LUMRYZ** requires the following rule(s) be met for renewal:

A. You have narcolepsy (a type of sleep condition)
B. You will NOT use Lumryz concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy) (such as Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
C. You meet ONE of the following:
    1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
    2. You have maintained an improvement in Epworth Sleepiness Scale (ESS: tool to measure your sleepiness) scores by at least 25 percent compared to baseline
    3. You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep) compared to baseline

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumryz.

REFERENCES

Lumryz [Prescribing Information]. Chesterfield, MO: Avadel CNS Pharmaceuticals, LLC; September 2024.

Created: 05/23
Effective: 08/28/26 Client Approval: 08/26 DMC Approval: 08/18/26

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SODIUM OXYBATE-XYREM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM OXYBATE	XYREM, SODIUM OXYBATE		18104	GPI-14 (62450060202020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic hypersomnia (IH) (ICD-10 G47.11, G47.12) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The requested medication will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])
   - The patient does NOT have cataplexy
   - The patient has a Multiple Sleep Latency Test (MSLT) showing less than two sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less
   - The patient has one or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
   - The patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months
   - The patient had a trial of or contraindication to ONE of the following preferred agents: armodafinil (Nuvigil), modafinil (Provigil)

     If yes, continue to #8.
     If no, continue to #2.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of cataplexy in narcolepsy (ICD-10 G47.411) and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs)
   - The patient has a SOREMP within 15 minutes of sleep onset
   - The patient has low orexin/hypocretin levels on a CSF assay

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has an Epworth Sleepiness Scale (ESS) score greater than 10
   - The requested medication will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])
   - The patient had a trial of or contraindication to TWO of the following preferred agents: venlafaxine, fluoxetine, TCA (tricyclic antidepressant, e.g., amitriptyline, clomipramine, imipramine)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy (ICD-10 G47.419) and meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has EDS persisting for at least 3 months
   - The patient has an Epworth Sleepiness Scale (ESS) score of more than 10
   - The requested medication will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

5. Does the patient have **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND at least 2 early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing a mean sleep latency of 8 minutes or less AND at least one early-onset REM sleep period (SOREMP) AND additionally one early-onset SOREMP (within approximately 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [**Note to pharmacist:** Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout *a single test* day at 2-hour intervals]
   - The patient has normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the patient 7 to 17 years of age **AND** meet the following criterion?
   - The patient had a trial of or contraindication to the following preferred agent: a generic stimulant (e.g., amphetamine sulfate, dextroamphetamine, methylphenidate)

   If yes, continue to #8.
   If no, continue to #7.

7. Is the patient 18 years of age or older **AND** meet the following criterion?
   - The patient had a trial of or contraindication to ONE of the following preferred agents from EACH of the following categories:
     - A generic typical stimulant (e.g., amphetamine sulfate, dextroamphetamine, methylphenidate)
     - Armodafinil (Nuvigil) OR modafinil (Provigil)

   If yes, continue to #8.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Is the request for generic sodium oxybate?

   If yes, **approve the generic only for 6 months by GPID or GPI-14 with a quantity limit of #18mL per day.**

   If no, continue to #9.

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

9. Is the request for brand Xyrem **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to generic sodium oxybate

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve. **(NOTE: Please enter a proactive PA for 6 months for generic sodium oxybate by GPID or GPI-14 with a quantity limit of #18mL per day.)**

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Idiopathic hypersomnia (IH: a type of sleep disorder)
      2. Cataplexy in narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
      3. Excessive daytime sleepiness (EDS) in narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

B. If you have idiopathic hypersomnia, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), or Restoril (temazepam)
4. You do NOT have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
5. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing less than 2 sleep-onset rapid eye movement (REM: a stage of sleep) sleep periods (SOREMP: time it takes to enter dream sleep), OR no SOREMPs if REM sleep latency (the time it takes to fall asleep and enter REM sleep stage) on a polysomnogram (type of sleep test) is 15 minutes or less
6. You have one or more Multiple Sleep Latency Test (MSLT: a type of sleep study) mean (average) sleep latency (the time it takes to fall asleep) of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on a 24-hour polysomnography (type of sleep test) or by wrist actigraphy (device that monitors movement) in association with a sleep log
7. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of an irrepressible need to sleep or daytime lapses into sleep for at least 3 months
8. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: armodafinil (Nuvigil), modafinil (Provigil)
9. If you are requesting brand Xyrem, you have tried or have a contraindication to (harmful for you to use) generic sodium oxybate

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

C. If you have cataplexy in narcolepsy, approval also requires:

1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You have an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
4. Your narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
   a. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs: time it takes to enter dream sleep)
   b. You have a sleep-onset rapid eye movement period (SOREMP: time it takes to enter dream sleep) within 15 minutes of sleep onset
   c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
5. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Restoril (temazepam)
6. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: venlafaxine, fluoxetine, a tricyclic anti-depressant (such as amitriptyline, clomipramine, imipramine)
7. If you are requesting brand Xyrem, you have tried or have a contraindication to (harmful for you to use) generic sodium oxybate

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SODIUM OXYBATE-XYREM

INITIAL CRITERIA (CONTINUED)

D. If you have excessive daytime sleepiness in narcolepsy, approval also requires:

1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You have excessive daytime sleepiness (EDS) persisting for at least 3 months
4. You have an Epworth Sleepiness Scale (ESS: tool to measure sleepiness) score of more than 10
5. You have ONE of the following:
   a. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency (the time it takes to fall asleep) of 8 minutes or less AND at least 2 early-onset rapid eye movement (REM: a stage of sleep) sleep test periods (SOREMPs: time it takes to enter dream sleep)
   b. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing an average sleep latency (the time it takes to fall asleep) of 8 minutes or less AND at least one early-onset rapid eye movement (REM: a stage of sleep) sleep test period (SOREMP: time it takes to enter dream sleep) AND additionally one early-onset SOREMP (within approximately 15 minutes or less) on a polysomnography (type of sleep test) the night before the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
   c. You have normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing normal levels of a chemical that helps with staying awake)
6. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic agent (drugs that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Restoril (temazepam)
7. If you are 7 to 17 years old, you have tried or have a contraindication to (harmful for you to use) the following preferred medication: a generic stimulant (such as amphetamine sulfate, dextroamphetamine, or methylphenidate)
8. If you are 18 years of age or older, you have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications from EACH of the following categories:
   a. A generic typical stimulant (such as amphetamine sulfate, dextroamphetamine, methylphenidate)
   b. Armodafinil (Nuvigil) OR modafinil (Provigil)
9. If you are requesting brand Xyrem, you have tried or have a contraindication to (harmful for you to use) generic sodium oxybate

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SODIUM OXYBATE-XYREM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy (Group G47.411, G47.419) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25 percent compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of idiopathic hypersomnia (IH) (ICD-10 G47.11, G47.12) and meet **ALL** of the following criteria?
   - The requested medication will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam])
   - The patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline OR maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25 percent compared to baseline

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM OXYBATE-XYREM

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Narcolepsy (uncontrollable daytime sleepiness)
   2. Idiopathic hypersomnia (IH: a type of sleep disorder)

B. If you have narcolepsy, renewal also requires:
   1. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam]
   2. You meet ONE of the following:
      a. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline (before treatment)
      b. You have maintained improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25 percent compared to baseline
      c. You have demonstrated improvement in sleep latency (the amount of time it takes to fall asleep)

C. If you have idiopathic hypersomnia, renewal also requires:
   1. You will NOT use the requested medication concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta [eszopiclone], Ambien [zolpidem], Restoril [temazepam]
   2. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline (before treatment) OR you have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25 percent compared to baseline

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xyrem.

REFERENCES

Xyrem [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.

Created: 11/13
Effective: 08/28/26 Client Approval: 08/26 DMC Approval: 08/18/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM PHENYLBUTYRATE	BUPHENYL, PHEBURANE, OLPRUVA, SODIUM PHENYLBUTYRATE	11317		GPI-10 (3090806000)	ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 Group E72.2) and meet **ALL** of the following criteria?
   - The patient's UCD is confirmed by enzymatic, biochemical or genetic testing
   - The requested medication will be used as adjunctive therapy along with dietary protein restriction
   - The patient's disorder cannot be managed by dietary protein restriction or amino acid supplementation alone

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for Buphenyl (sodium phenylbutyrate)?

   If yes, **approve the requested formulation for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **Buphenyl tablets: #40 per day.**
   - **Buphenyl powder: #21.3 grams per day.**

   If no, continue to #3.

3. Is the request for Pheburane, and the patient meets **ALL** of the following criteria?
   - The patient had a trial of or contraindication to generic sodium phenylbutyrate powder
   - The patient is unable to swallow Buphenyl (sodium phenylbutyrate) tablet

   If yes, **approve Pheburane for 12 months by GPID or GPI-14 with a quantity limit of #41.5grams per day.**

   If no, continue to #4.

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SODIUM PHENYLBUTYRATE

INITIAL CRITERIA (CONTINUED)

4. Is the request for Olpruva, and the patient meets **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient had a trial of or contraindication to generic sodium phenylbutyrate powder
   - The patient is unable to swallow Buphenyl (sodium phenylbutyrate) tablet

   If yes, **approve the requested strength of Olpruva for 12 months by GPID or GPI-14 as follows:**
   - **2 grams: #12 per day.**
   - **3 grams: #12 per day.**
   - **4 grams: #15 per day.**
   - **5 grams: #12 per day.**
   - **6 grams: #9 per day.**
   - **6.67 grams: #9 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for approval:

   A. You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
   B. Your disorder is confirmed by enzymatic, biochemical or genetic testing (types of lab tests)
   C. The requested medication will be used as adjunctive (add-on) therapy along with dietary protein restriction
   D. Your disorder cannot be managed by dietary protein restriction or amino acid supplementation alone
   E. If your request is for Pheburane, approval also requires:
      1. You have tried or have a contraindication to (harmful for you to use) generic sodium phenylbutyrate powder
      2. You are unable to swallow Buphenyl (sodium phenylbutyrate) tablet
   F. If your request is for Olpruva, approval also requires:
      1. You are 1 year of age or older
      2. You have tried or have a contraindication to (harmful for you to use) generic sodium phenylbutyrate powder
      3. You are unable to swallow Buphenyl (sodium phenylbutyrate) tablet

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SODIUM PHENYLBUTYRATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) (ICD-10 Group E72.2) **AND** meet the following criterion?
   - The patient has experienced a clinical benefit from baseline (e.g., normal fasting glutamine, low- normal fasting ammonia levels, mental status clarity)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for Buphenyl or Pheburane?

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 as follows:**
   - **Buphenyl tablets: #40 per day.**
   - **Buphenyl powder: #21.3 grams per day.**
   - **Pheburane: #41.5 grams per day.**

   If no, continue to #3.

3. Is the request for Olpruva?

   If yes, **approve the requested strength of Olpruva for 12 months by GPID or GPI-14 as follows:**
   - **2 grams: #12 per day.**
   - **3 grams: #12 per day.**
   - **4 grams: #15 per day.**
   - **5 grams: #12 per day.**
   - **6 grams: #9 per day.**
   - **6.67 grams: #9 per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM PHENYLBUTYRATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl, Pheburane, Olpruva)** requires the following rule(s) be met for renewal:

A. You have a urea cycle disorder (UCD: a genetic disorder that causes high ammonia levels in the blood)
B. You have experienced a clinical benefit from baseline (for example you have normal fasting glutamine levels, low-normal fasting ammonia levels, mental status clarity)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Buphenyl, Olpruva, or Pheburane.

REFERENCES

Buphenyl [Prescribing Information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; April 2023.
Olpruva [Prescribing Information]. Newton, MA: Acer Therapeutics Inc.; October 2025.
Pheburane [Prescribing Information]. Princeton, NJ: Medunik USA, Inc.; August 2023.

Created: 08/19
Effective: 02/11/26 Client Approval: 02/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SODIUM/CALCIUM/MAG/POT OXYBATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SODIUM, CALCIUM, MAG, POT OXYBATE	XYWAV	46743		GPI-10 (6245990420)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic hypersomnia (IH) (ICD-10 G47.11, G47.12) and the diagnosis is confirmed by **ALL** of the following criteria?
   - The patient does not have cataplexy
   - The patient has a Multiple Sleep Latency Test (MSLT) showing less than 2 sleep-onset REM sleep periods (SOREMP) OR no SOREMPs if REM sleep latency on polysomnogram is 15 minutes or less
   - The patient has 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
   - The patient has had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND the patient has experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - Xywav will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
   - The patient had a trial and failure of or contraindication to ONE of the following preferred agents: armodafinil, modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of cataplexy in narcolepsy (ICD-10 G47.411) and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs)
   - The patient has a SOREMP within 15 minutes of sleep onset
   - The patient has low orexin/hypocretin levels on CSF assay

   If yes, continue to #4.
   If no, continue to #5.

4. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has an Epworth Sleepiness Scale (ESS) score greater than 10
   - Xywav will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
   - The patient has tried TWO of the following preferred agents: venlafaxine, fluoxetine, TCA (e.g., amitriptyline, clomipramine, imipramine)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) in narcolepsy (ICD-10 G47.419) and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND two or more early-onset REM sleep periods (SOREMPs)
   - The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one or more early-onset REM sleep periods (SOREMPS) AND additionally one early-onset SOREMP (within approx. 15 minutes or less) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of EDS [**Note to pharmacist**: Multiple Sleep Latency Test (MSLT) is a guideline-supported instrument for assessing the severity and likelihood of narcolepsy, which consists of five 20-minute nap periods spread throughout a single test day at 2-hour intervals]
   - The patient has normal orexin/hypocretin levels on a CSF assay

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 7 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has EDS persisting for at least 3 months and an Epworth Sleepiness Scale (ESS) score greater than 10
   - Xywav will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])
   - The patient meets ONE of the following:
     - The patient is 7 to 17 years of age AND had a trial and failure of or contraindication to the following preferred agent: a generic stimulant (e.g., amphetamine, dextroamphetamine, methylphenidate)
     - The patient is 18 years of age or older AND had a trial and failure of or contraindication to ONE of the following preferred agents:
       - A generic typical stimulant (e.g., amphetamine sulfate, dextroamphetamine, methylphenidate)
       - Armodafinil OR modafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Idiopathic hypersomnia (IH: a type of sleep disorder)
      2. Cataplexy in narcolepsy (a type of sleep condition with extreme drowsiness with sudden and uncontrollable muscle weakness)
      3. Excessive daytime sleepiness (EDS) in narcolepsy (a type of sleep condition with overwhelming daytime drowsiness)

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

B. If you have idiopathic hypersomnia, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
4. Your diagnosis is confirmed by ALL of the following:
   a. You do not have cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
   b. You have a Multiple Sleep Latency Test (MSLT: a type of sleep study) showing less than 2 sleep-onset REM sleep periods (SOREMP: time it takes to enter dream sleep) OR no SOREMPs if REM sleep latency on polysomnogram (type of sleep test) is 15 minutes or less
   c. You have 1 or more MSLT mean sleep latency of 8 minutes or less, OR total 24-hour sleep is 660 minutes or more on 24-hour polysomnography or by wrist actigraphy (device that monitors movement) in association with a sleep log
   d. You have had insufficient sleep syndrome ruled out, AND there is no better explanation by another sleep/medical/psychiatric disorder or use of drugs/medications, AND you have experienced daily periods of irrepressible need to sleep or daytime lapses into sleep for at least 3 months
5. You tried and failed or have a contraindication to (harmful for you to use) ONE of the following preferred medications: armodafinil, modafinil

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

C. If you have cataplexy in narcolepsy, approval also requires:

1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You have an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
4. Your narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
   a. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both a mean sleep latency of 8 minutes or less AND two or more sleep-onset rapid eye movement periods (SOREMPs: time it takes to enter dream sleep)
   b. You have a sleep-onset rapid eye movement period (SOREMP: time it takes to enter dream sleep) within 15 minutes of sleep onset
   c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
5. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
6. You have tried TWO of the following preferred medications: venlafaxine, fluoxetine, tricyclic anti-depressants (such as amitriptyline, clomipramine, imipramine)

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SODIUM/CALCIUM/MAG/POT OXYBATE

INITIAL CRITERIA (CONTINUED)

D. If you have excessive daytime sleepiness in narcolepsy, approval also requires:

1. You are 7 years of age or older
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You have EDS persisting for at least 3 months and an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
4. Your narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
   a. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs: time it takes to enter dream sleep)
   b. A Multiple Sleep Latency Test (MSLT: a type of sleep study) showing both an average sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP: time it takes to enter dream sleep) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night before the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
   c. You have normal orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have normal levels of a chemical that helps with staying awake)
5. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
6. If you are 7 to 17 years old, you tried and failed or have a contraindication to (harmful for you to use) the following preferred medication: a generic stimulant (such as amphetamine, dextroamphetamine, methylphenidate)
7. If you are 18 years or older, you tried and failed or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. A generic typical stimulant (such as amphetamine sulfate, dextroamphetamine, methylphenidate)
   b. Armodafinil OR modafinil

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SODIUM/CALCIUM/MAG/POT OXYBATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy (Group G47.41) **AND** meet the following criterion?
   - Xywav will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of cataplexy symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25 percent compared to baseline
   - The patient has demonstrated improvement in sleep latency from baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of idiopathic hypersomnia (IH) (ICD-10 G47.11, G47.12) **AND** meet the following criterion?
   - Xywav will NOT be used concurrently with a sedative hypnotic agent (e.g., Lunesta [eszopiclone], Ambien [zolpidem], Sonata [zaleplon], estazolam, Restoril [temazepam], Halcion [triazolam], flurazepam, quazepam, Belsomra [suvorexant])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient meet **ONE** of the following criteria?
   - The patient has demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline
   - The patient has maintained an improvement in Epworth Sleepiness Scale (ESS) scores by at least 25 percent compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #18mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SODIUM/CALCIUM/MAG/POT OXYBATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Narcolepsy (uncontrollable daytime sleepiness)
   2. Idiopathic hypersomnia (IH: a type of sleep disorder)

B. If you have narcolepsy, renewal also requires:
   1. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
   2. You meet ONE of the following:
      a. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline (before treatment)
      b. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25 percent compared to baseline
      c. You have demonstrated improvement in sleep latency (the amount of time it takes you to fall asleep)

C. If you have idiopathic hypersomnia, renewal also requires:
   1. You will NOT use Xywav concurrently (at the same time) with a sedative hypnotic medication (medications that make you sleepy), such as Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra (suvorexant)
   2. You meet ONE of the following:
      a. You have demonstrated improvement of idiopathic hypersomnia symptoms compared to baseline (before treatment)
      b. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25 percent compared to baseline

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SODIUM/CALCIUM/MAG/POT OXYBATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xywav.

REFERENCES

Xywav [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; April 2023.

Created: 11/20
Effective: 08/28/26 Client Approval: 08/26 DMC Approval: 08/18/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR	SOVALDI	40795		GPI-10 (1235308000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ONE** of the following criteria?
- The patient has genotype 2 or 3 infection AND is 3 years of age or older
- The patient has genotype 1 or 4 infection AND is 18 years of age or older

If yes, continue to #2.
If no, continue to #10.

2. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
- The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- Sovaldi will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin [rifapentine], St. John's wort, Aptivus [tipranavir]/ritonavir)
- Solvadi will be used concurrently with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have genotype 2 infection and meet **ALL** of the following criteria?
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - Sovaldi will be used with ribavirin
   - The patient is 3 years of age or older AND had an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Mavyret

   If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths and formulations as follows:**
   - **400mg tablets: #1 per day.**
   - **200mg tablets: #1 per day.**
   - **200mg pellets: #2 per day.**
   - **150mg pellets: #1 per day.**

   If no, continue to #5.

5. Does the patient have genotype 3 infection and meet **ALL** of the following criteria?
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - Sovaldi will be used with ribavirin
   - The patient is 3 years of age or older AND had an intolerance or contraindication to ONE of the following preferred agents: Epclusa, Mavyret

   If yes, **approve for 24 weeks by GPID or GPI-14 for all strengths and formulations as follows:**
   - **400mg tablets: #1 per day.**
   - **200mg tablets: #1 per day.**
   - **200mg pellets: #2 per day.**
   - **150mg pellets: #1 per day.**

   If no, continue to #6.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have genotype 1 or 4 infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is treatment-naïve
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - Sovaldi will be used with peginterferon alfa and ribavirin
   - The patient had an intolerance or contraindication to ONE of the following preferred agents: Harvoni, Epclusa, Mavyret

   If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths and formulations as follows:**
   - **400mg tablets: #1 per day.**
   - **200mg tablets: #1 per day.**
   - **200mg pellets: #2 per day.**
   - **150mg pellets: #1 per day.**

   If no, continue to #7.

7. Does the patient have genotype 1 infection and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is treatment-naïve
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - Sovaldi will be used with ribavirin
   - The patient has a contraindication to interferon (interferon ineligible)
   - The patient had an intolerance or contraindication to ONE of the following preferred agents: Harvoni, Epclusa, Mavyret

   If yes, **approve for 24 weeks by GPID or GPI-14 for all strengths and formulations as follows:**
   - **400mg tablets: #1 per day.**
   - **200mg tablets: #1 per day.**
   - **200mg pellets: #2 per day.**
   - **150mg pellets: #1 per day.**

   If no, continue to #8.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

8. Is the request to prevent post-transplant HCV reinfection and the patient meets **ALL** of the following criteria?
   - The patient has hepatocellular carcinoma (ICD-10 C22.0)
   - The patient is awaiting liver transplantation
   - Sovaldi will be used with ribavirin as pre-transplant treatment

   If yes, **approve for 48 weeks by GPID or GPI-14 for all strengths and formulations as follows:**
   - **400mg tablets: #1 per day.**
   - **200mg tablets: #1 per day.**
   - **200mg pellets: #2 per day.**
   - **150mg pellets: #1 per day.**

   If no, continue to #9.

9. Has the patient previously failed treatment with Mavyret (glecaprevir/pibrentasvir) OR Vosevi (sofosbuvir/velpatasvir/voxilaprevir) and meets **ALL** of the following criteria?
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - Sovaldi will be used with Mavyret (glecaprevir/pibrentasvir) AND ribavirin

   If yes, **approve for 16 weeks by GPID or GPI-14 for all strengths and formulations as follows:**
   - **400mg tablets: #1 per day.**
   - **200mg tablets: #1 per day.**
   - **200mg pellets: #2 per day.**
   - **150mg pellets: #1 per day.**

   If no, continue to #10.

10. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

    If yes, **approve as indicated per guidance in AASLD/IDSA.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR (Sovaldi)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You have genotype 2 or 3 infection (types of hepatitis C virus) and are 3 years of age or older OR you have genotype 1 or 4 infection (types of hepatitis C virus) and are 18 years of age or older
C. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
D. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
E. You will NOT use Sovaldi concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, Priftin [rifapentine], St. John's wort, Aptivus [tipranavir]/ritonavir)
F. You will NOT use Sovaldi concurrently (at the same time) with Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Vosevi (velpatasvir/sofosbuvir/voxilaprevir), or Zepatier (elbasvir/grazoprevir)
G. If you have genotype 2 infection, approval also requires:
    1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
    2. Sovaldi will be used with ribavirin
    3. You are 3 years of age or older AND had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa, Mavyret
H. If you have genotype 3 infection, approval also requires:
    1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
    2. Sovaldi will be used with ribavirin
    3. You are 3 years of age or older AND had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Epclusa, Mavyret

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

I. If you have genotype 1 infection, approval also requires:
1. You are 18 years of age or older
2. You are treatment-naïve (no prior treatment)
3. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
4. Sovaldi will be used with peginterferon alfa and ribavirin OR Sovaldi will be used with ribavirin if you have a contraindication to (harmful for you to use) interferon
5. You had an intolerance (side effect) or contraindication to ONE of the following preferred medications: Harvoni, Epclusa, Mavyret

J. If you have genotype 4 infection, approval also requires:
1. You are 18 years of age or older
2. You are treatment-naïve (no prior treatment)
3. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
4. Sovaldi will be used with peginterferon alfa and ribavirin
5. You had an intolerance (side effect) or contraindication to (harmful for you to use) ONE of the following preferred medications: Harvoni, Epclusa, Mavyret

K. If Sovaldi will be used to prevent post-transplant HCV reinfection (getting infected again with HCV after transplant), approval also requires:
1. You have hepatocellular carcinoma (HCC: a type of liver cancer)
2. You are awaiting liver transplantation (you have not yet replaced your liver)
3. Sovaldi will be used with ribavirin as pre-transplant (before transplant) treatment

L. If you had a previous treatment failure with Mavyret (glecaprevir/pibrentasvir) OR Vosevi (sofosbuvir/velpatasvir/voxilaprevir), approval also requires:
1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
2. Sovaldi will be used with Mavyret (glecaprevir/pibrentasvir) AND ribavirin

M. Sovaldi will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

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SOFOSBUVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sovaldi.

REFERENCES

Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; December 2024.
Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, and Managing. Available online at http://www.hcvguidelines.org/full-report-view Accessed April 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR	EPCLUSA, SOFOSBUVIR-VELPATASVIR	43561		GPI-10 (1235990265)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
- The patient is 3 years of age or older
- The patient has genotype 1, 2, 3, 4, 5, or 6 infection

If yes, continue to #2.
If no, continue to #6.

2. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
- The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- The requested medication will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], efavirenz-containing HIV regimens, rosuvastatin at doses greater than 10mg, Aptivus [tipranavir]/ritonavir, topotecan, St. John's wort)
- The requested medication will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient does not have cirrhosis
   - The patient has compensated cirrhosis (Child-Pugh A)
   - The patient has decompensated cirrhosis (moderate or severe hepatic impairment; Child- Pugh B or C) AND the requested medication will be used with ribavirin

   If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths and formulations as follows:**
   - **400mg-100mg tablets: #1 per day.**
   - **200mg-50mg tablets: #1 per day.**
   - **200mg-50mg pellets: #2 per day.**
   - **150mg-37.5mg pellets: #1 per day.**

   If no, continue to #5.

5. Does the patient have decompensated cirrhosis and meet **ONE** of the following criteria?
   - The patient has a contraindication to ribavirin (ribavirin ineligible)
   - The patient has failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir/ribavirin) AND the requested medication will be used with ribavirin
   - The patient has failed prior treatment with an NS5A inhibitor-based regimen (e.g., Harvoni [ledipasvir/sofosbuvir]) AND the requested medication will be used with ribavirin
   - The patient is post-liver transplant, treatment-experienced, AND the requested medication will be used with ribavirin

   If yes, **approve for 24 weeks by GPID or GPI-14 for all strengths and formulations as follows:**
   - **400mg-100mg tablets: #1 per day.**
   - **200mg-50mg tablets: #1 per day.**
   - **200mg-50mg pellets: #2 per day.**
   - **150mg-37.5mg pellets: #1 per day.**

   If no, continue to #6.

6. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

   If yes, **approve as indicated per guidance in AASLD/IDSA.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 3 years of age or older
C. You have genotype 1, 2, 3, 4, 5, or 6 hepatitis C infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You will NOT use the requested medication concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, carbamazepine, phenytoin, phenobarbital, rifampin, rifabutin, Priftin [rifapentine], efavirenz-containing HIV [human immunodeficiency virus] regimens, rosuvastatin at doses greater than 10mg, Aptivus [tipranavir]/ritonavir, topotecan, St. John's wort)
G. You will NOT use the requested medication concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), Mavyret (pibrentasvir/glecaprevir), or Vosevi (velpatasvir/sofosbuvir/voxilaprevir)
H. You meet ONE of the following:
    1. You do not have cirrhosis (liver damage and scarring)
    2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage)
    3. You have decompensated cirrhosis (a condition where there is liver damage and scarring with major symptoms) (moderate or severe liver impairment; Child-Pugh B or C [a score that evaluates the severity of liver damage]), and you meet ONE of the following:
        a. You will use the requested medication with ribavirin
        b. You have a contraindication to (harmful for you to use) ribavirin
        c. You have failed prior treatment with a sofosbuvir-based regimen (such as sofosbuvir/ribavirin) AND the requested medication will be used with ribavirin
        d. You have failed prior treatment with an NS5A inhibitor-based regimen (such as Harvoni [ledipasvir/sofosbuvir]) AND the requested medication will be used with ribavirin
        e. You received a liver transplant (replaced your liver), are treatment-experienced (failed prior treatment), AND the requested medication will be used with

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ribavirin

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SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

I. The requested medication will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Epclusa.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed August 17, 2026.

Epclusa [Prescribing Information]. Foster City, CA: Gilead Sciences; April 2022.

Created: 07/16
Effective: 09/01/26 Client Approval: 08/26 DMC Approval: 08/18/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR	VOSEVI	44428		GPI-10 (1235990380)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C virus (HCV) (ICD-10 B18.2) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient has genotype 1, 2, 3, 4, 5, or 6 infection

If yes, continue to #2.
If no, continue to #8.

2. Does the patient have an HCV RNA level within the past 6 months?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ANY** of the following criteria?
- The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- The patient has moderate or severe hepatic impairment (decompensated cirrhosis; Child-Pugh B or C)
- Vosevi will be used concurrently with any medication with drug interactions that are contraindicated or not recommended per the prescribing information (e.g., amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, rifabutin, Priftin [rifapentine], rosuvastatin, pitavastatin, pravastatin at doses greater than 40mg, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, St. John's wort, HIV regimens containing atazanavir, lopinavir, Aptivus [tipranavir]/ritonavir, or efavirenz)
- Vosevi will be used concurrently with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Is the patient treatment-naive and meets **ALL** of the following criteria?
   - The patient has genotype 3 infection
   - The patient has compensated cirrhosis
   - The patient has NS5A RAS Y93H polymorphism

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #5.

5. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - The patient has failed prior treatment with a full course of an HCV regimen containing an NS5A inhibitor (e.g., Harvoni [ledipasvir/sofosbuvir], Mavyret [pibrentasvir/glecaprevir]) or a DAA (e.g., Olysio [simeprevir]/peginterferon/ribavirin, Epclusa [velpatasvir/sofosbuvir]) if post-liver or kidney transplant

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #6.

6. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - The patient has failed prior treatment with a sofosbuvir-based regimen (e.g., Epclusa [sofosbuvir/velpatasvir], sofosbuvir with ribavirin, sofosbuvir with Olysio [simeprevir])

   If yes, **approve for 12 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #7.

7. Is the patient treatment-experienced and meets **ALL** of the following criteria?
   - The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
   - The patient failed prior treatment with Vosevi
   - Vosevi will be used with ribavirin

   If yes, **approve for 24 weeks by HICL or GPI-10 for #1 per day.**
   If no, continue to #8.

8. Is the requested regimen recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment?

   If yes, **approve as indicated per guidance in AASLD/IDSA.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (Vosevi)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C virus (HCV: liver inflammation caused by a type of virus)
B. You are 18 years of age or older
C. You have genotype 1, 2, 3, 4, 5 or 6 infection (types of hepatitis C virus)
D. You have an HCV RNA level (a measure of the amount of hepatitis C virus in the blood) within the past 6 months
E. You do NOT have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
F. You do NOT have moderate or severe liver impairment (decompensated cirrhosis [a condition where there is liver damage and scarring with major symptoms]; Child-Pugh B or C [a score that evaluates the severity of liver damage])
G. You will NOT use Vosevi concurrently (at the same time) with any medication with drug interactions that are contraindicated (harmful for you to use) or not recommended per the prescribing information (such as amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, rifabutin, Priftin [rifapentine], rosuvastatin, pitavastatin, pravastatin at doses greater than 40mg, cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, St. John's wort, HIV (human immunodeficiency virus) regimens containing atazanavir, lopinavir, Aptivus [tipranavir]/ritonavir, or efavirenz)
H. You will NOT use Vosevi concurrently (at the same time) with Sovaldi (sofosbuvir; as a single agent), Epclusa (velpatasvir/sofosbuvir), Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir), or Mavyret (pibrentasvir/glecaprevir)
I. **If you are treatment-naïve (no prior treatment), approval also requires**:
    1. You have genotype 3 infection
    2. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms)
    3. You have NS5A resistance-associated substitution (RAS) Y93H polymorphism (variations in a type of hepatitis C virus protein)

(Denial text continued on next page)

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

GUIDELINES FOR USE (CONTINUED)

J. **If you are treatment-experienced (failed prior treatment), approval also requires**:
   1. You have compensated cirrhosis (a condition where there is liver damage and scarring without any major symptoms) (Child-Pugh A: a score that evaluates the severity of liver damage) OR you do not have cirrhosis (liver damage and scarring)
   2. You meet ONE of the following:
      a. You have failed a full course of a regimen containing an NS5A inhibitor (such as Harvoni [ledipasvir/sofosbuvir], Mavyret [pibrentasvir/glecaprevir]) or a direct-acting antiviral (such as Olysio [simeprevir]/peginterferon/ribavirin, Epclusa [velpatasvir/sofosbuvir]) if post-liver or kidney transplant (replaced your liver or kidney)
      b. You have failed prior treatment with a sofosbuvir-based regimen (such as Epclusa [sofosbuvir/velpatasvir], sofosbuvir with ribavirin, sofosbuvir with Olysio [simeprevir])
      c. You have failed prior treatment with Vosevi AND Vosevi will be used with ribavirin

K. Vosevi will also be approved for any other regimen/condition not listed above that is recommended by the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidance for Hepatitis C Treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vosevi.

REFERENCES

Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed November 30, 2023.

Vosevi [Prescribing Information]. Foster City, CA: Gilead Sciences; November 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/22/24
Created: 08/17
Client Approval: 06/24
P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOFPIRONIUM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOFPIRONIUM BROMIDE	SOFDRA	49707		GPI-10 (9097008320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary axillary hyperhidrosis (ICD-10 L74.510) and meet **ALL** of the following criteria?
- The patient is 9 years of age or older
- The patient has primary axillary hyperhidrosis as evidenced by focal, visible, excessive sweating of at least 6 months duration with all secondary causes ruled out
- Sofdra will NOT be used concurrently with other topical anticholinergics indicated for primary axillary hyperhidrosis (e.g., Qbrexza [glycopyrronium tosylate])

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **TWO** of the following criteria?
- Symptoms occur bilaterally
- Symptoms impair daily activities
- The patient has at least one episode per week
- Onset occurred prior to the patient turning 25 years of age
- The patient has a family history of primary axillary hyperhidrosis
- Symptoms do not occur during sleep

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.34mL per day.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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SOFPIRONIUM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOFPIRONIUM (Sofdra)** requires the following rule(s) be met for approval:

A. You have primary axillary hyperhidrosis (excessive underarm sweating)
B. You are 9 years of age or older
C. You have primary axillary hyperhidrosis (excessive underarm sweating) as evidenced by focal (limited to a particular area of the body), visible, excessive sweating of at least 6 months duration with all secondary causes (caused by another medical condition) ruled out
D. You will NOT use Sofdra concurrently (at the same time) with other topical anticholinergics used for primary axillary hyperhidrosis (excessive underarm sweating) (such as Qbrexza [glycopyrronium tosylate])
E. You have at least two of the following:
    1. Symptoms occur bilaterally (on both sides of the body)
    2. Symptoms impair daily activities
    3. You have at least one episode per week
    4. Onset occurred before you turn(ed) 25 years old
    5. You have a family history of primary axillary hyperhidrosis (excessive underarm sweating)
    6. Symptoms do not occur during sleep

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sofdra.

REFERENCES

Sofdra [Prescribing Information]. Wayne, PA: Botanix SB Inc.; June 2024.

Created: 07/24
Effective: 08/01/26 DMC Approval: 07/21/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLIFENACIN SUSPENSION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOLIFENACIN SUCCINATE	VESICARE LS		47476	GPI-14 (54100055201820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurogenic detrusor overactivity (ICD-10 N32.81) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The patient had a trial of or contraindication to TWO of the following:
     - Anticholinergics (e.g., oxybutynin)
     - Beta-3 agonists (e.g., Myrbetriq [mirabegron])
   - The patient is unable to swallow oral solifenacin tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #10mL per day.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLIFENACIN SUSPENSION (Vesicare LS)** requires the following rule(s) be met for approval:
   A. You have neurogenic detrusor overactivity (type of bladder condition)
   B. You are 2 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) TWO of the following:
      1. Anticholinergics (such as oxybutynin)
      2. Beta-3 agonists (such as Myrbetriq [mirabegron])
   D. You are unable to swallow oral solifenacin tablets

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vesicare LS.

REFERENCES

Vesicare LS [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; June 2020.

Created: 05/21
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOLRIAMFETOL	SUNOSI	45666		GPI-10 (6137007020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419) and the narcolepsy diagnosis is confirmed by **ONE** of the following criteria?
   - The patient has had a sleep study (e.g., polysomnography, multiple sleep latency test [MSLT])
   - The patient has had a measurement of orexin levels

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
   - The patient has an Epworth Sleepiness Scale (ESS) score greater than 10
   - The patient had a trial of or contraindication to ONE of the following preferred agents: a generic typical stimulant (e.g., amphetamine sulfate, methylphenidate), modafinil, armodafinil

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOLRIAMFETOL

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) (ICD-10 G47.10) with obstructive sleep apnea (OSA) (ICD-10 G47.33) and the OSA diagnosis is confirmed by **ONE** of the following criteria?
   - Polysomnography
   - Home sleep apnea testing devices
   - Hospital-based bedside monitoring

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
   - The patient has EDS with an Epworth Sleepiness Scale (ESS) score greater than 10
   - The patient had a trial of or contraindication to ONE of the following preferred agents: modafinil, armodafinil
   - The patient is in ongoing treatment to address the obstructive causes of OSA, for at least one month since initiation

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Excessive daytime sleepiness (EDS) with narcolepsy (a sleep condition with overwhelming daytime drowsiness)
      2. Excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA) (a type of sleep condition due to a disorder where airflow is blocked during sleep)

   (Initial denial text continued on the next page)

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SOLRIAMFETOL

INITIAL CRITERIA (CONTINUED)

B. If you have excessive daytime sleepiness with narcolepsy, approval also requires:
1. Your diagnosis of narcolepsy (a type of sleep condition) is confirmed by ONE of the following:
   i. You have had a sleep study (such as polysomnography [type of sleep test], multiple sleep latency test [MSLT: a type of sleep study])
   ii. You have had a measurement of orexin levels (test showing you have low levels of a chemical that helps with staying awake)
2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor), psychiatrist (a type of mental health doctor), or specialist in sleep medicine
3. You have an Epworth Sleepiness Scale (ESS: tool to measure sleepiness) score of more than 10
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: a generic typical stimulant (such as amphetamine sulfate, methylphenidate), modafinil, armodafinil

C. If you have excessive daytime sleepiness with obstructive sleep apnea, approval also require:
1. Your diagnosis of obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep) is confirmed by a polysomnography (a type of sleep test), home sleep apnea testing devices, or hospital-based bedside monitoring
2. You have excessive daytime sleepiness with an Epworth Sleepiness Scale (ESS: tool to measure sleepiness) score of more than 10
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: modafinil, armodafinil
4. You have been on a treatment for the obstructive causes of obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep), for at least one month since initiation

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Excessive daytime sleepiness (EDS) with narcolepsy (ICD-10 G47.419)
   - Excessive daytime sleepiness (EDS) (ICD-10 G47.10) with obstructive sleep apnea (OSA) (ICD-10 G47.33)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient demonstrated at least 25 percent improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Excessive daytime sleepiness (EDS) with narcolepsy (a sleep condition with overwhelming daytime drowsiness)
      2. Excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA) (a type of sleep condition due to a disorder where airflow is blocked during sleep)
   B. You have shown improvement in Epworth Sleepiness Scale (ESS: tool to measure sleepiness) scores by at least 25 percent compared to baseline (before treatment)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Sunosi.

REFERENCES
Sunosi [Prescribing Information]. New York, NY: Axsome Therapeutics, Inc.; May 2026.

Created: 07/19
Effective: 08/21/26 Client Approval: 08/26 DMC Approval: 08/18/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMAPACITAN-BECO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMAPACITAN-BECO	SOGROYA	46831		GPI-10 (3010000720)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 2.5 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity that is less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

4. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 Group E34.3, E23.0), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, continue to #5.
   If no, continue to #7.

5. Is the patient's GHD caused by a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days**.
   If no, continue to #6.

6. Is the patient's GHD confirmed by **ONE** of the following growth hormone stimulation tests?
   - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
   - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
   - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10**.
   If no, continue to #8.

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SOMAPACITAN-BECO

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of growth failure associated with Noonan syndrome (ICD-10 Q87.19) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for approval:

   A. You meet ONE of the following:
      1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
      2. You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
      3. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
      4. You have growth failure associated with Noonan syndrome (a type of genetic disorder)

   B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:
      1. You are 2.5 to 17 years of age
      2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
      3. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand
      4. You meet ONE of the following:
         a. Your height is at least 2 standard deviations (SD) below the mean (average) height for children of the same age and gender
         b. Your height velocity is less than the 25th percentile for your age
         c. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
      5. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

   (Initial denial text continued on next page)

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SOMAPACITAN-BECO

INITIAL CRITERIA (CONTINUED)

C. If you are an adult patient with growth hormone deficiency, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
3. You meet ONE of the following:
   a. Your growth hormone deficiency is caused by a congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests (tests that measure the body's ability to produce growth hormone):
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
4. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

D. If you have short stature born small for gestational age, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
5. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

E. If you have growth failure associated with Noonan syndrome, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
3. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
4. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

F. Request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

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SOMAPACITAN-BECO

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 2.5 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), OR the patient has not completed prepubertal growth
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient has an annual growth velocity of at least 1 cm compared with what was observed from the previous year if close to the terminal phase of puberty

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMAPACITAN-BECO

RENEWAL CRITERIA (CONTINUED)

4. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 Group E34.3, E23.0), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has achieved or maintained a response to therapy as evidenced by clinical treatment goals (e.g., improved body composition, lipid panel, bone health)
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, continue to #5.

5. Does the patient have **ONE** of the following diagnoses?
   - Short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1)
   - Growth failure associated with Noonan syndrome (ICD-10 Q87.19)

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand, or the patient has not completed prepubertal growth)
   - The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year, OR an annual growth velocity of at least 1 cm compared with what was observed from the previous year for patients that are near the terminal phase of puberty
   - Sogroya will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMAPACITAN-BECO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMAPACITAN-BECO (Sogroya)** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
   1. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   2. You are an adult patient with growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   3. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
   4. You have growth failure associated with Noonan syndrome (a type of genetic disorder)

B. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
   1. You are 2.5 to 17 years of age
   2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal (before puberty) growth
   4. You meet ONE of the following:
      a. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
      b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty
   5. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

(Renewal denial text continued on next page)

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SOMAPACITAN-BECO

RENEWAL CRITERIA (CONTINUED)

C. If you are an adult patient with growth hormone deficiency, renewal also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
3. You have achieved or maintained a response to therapy as evidenced by clinical treatment goals (such as improved body composition, lipid [fat] panel, bone health)
4. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

D. If you have short stature born small for gestational age OR growth failure associated with Noonan syndrome, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
2. Your epiphyses (end part of long bone) are not closed as confirmed by radiograph (a type of imaging test) of the wrist and hand OR you have not completed prepubertal (before puberty) growth
3. Your growth velocity is at least 2 cm compared with what was observed from the previous year OR your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty
4. You will NOT use Sogroya concurrently (at the same time) with Increlex (mecasermin)

E. Renewal request for Sogroya will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sogroya.

REFERENCES

Sogroya [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; February 2026.

Created: 05/23
Effective: 05/13/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROGON-GHLA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROGON-GHLA	NGENLA	47896		GPI-10 (3010001500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 3 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - Ngenla will NOT be used concurrently with Increlex (mecasermin)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Skytrofa (lonapegsomatropin-tcgd), Sogroya (somapacitan-beco)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient has a height velocity that is less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR has an insulin-like growth factor 1 (IGF-1) that is at least 2 SD below the mean for the same age and gender

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROGON-GHLA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for approval:

A. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
B. You are 3 to 17 years of age
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed, as confirmed by a radiograph (type of imaging test) of the wrist and hand
E. You will NOT use Ngenla concurrently (at the same time) with Increlex (mecasermin)
F. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Skytrofa (lonapegsomatropin-tcgd), Sogroya (somapacitan-beco)
G. You meet ONE of the following:
    1. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
    2. Your height velocity is less than the 25th percentile for your age
    3. You have a low peak growth hormone level (less than 10 ng/mL) on TWO growth hormone stimulation tests, OR an insulin-like growth factor 1 (IGF-1) level that is at least 2 standard deviations below the mean for your age and gender
H. Request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROGON-GHLA

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ISS) (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #2.

2. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 3 to 17 years of age
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), OR the patient has not completed prepubertal growth
   - Ngenla will NOT be used concurrently with Increlex (mecasermin)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year
   - The patient has an annual growth velocity of at least 1 cm compared with what was observed from the previous year if close to the terminal phase of puberty

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROGON-GHLA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROGON-GHLA (Ngenla)** requires the following rule(s) be met for renewal:

A. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
B. You are 3 to 17 years of age
C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor)
D. Your epiphyses (end part of long bone) are NOT closed as confirmed by a radiograph (type of imaging test) of the wrist and hand, OR you have not completed prepubertal growth
E. You will NOT use Ngenla concurrently (at the same time) with Increlex (mecasermin)
F. You meet ONE of the following:
    1. Your annual growth velocity (rate of growth) is at least 2 cm compared with what was observed from the previous year
    2. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are close to the terminal (final) phase of puberty
G. Renewal request for Ngenla will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (ISS: a type of growth condition)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ngenla.

REFERENCES

Ngenla [Prescribing Information]. New York, NY: Pfizer Laboratories; July 2025.

Created: 08/23
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - ZORBTIVE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	ZORBTIVE		12767	GPI-14 (30100020102132)	BRAND = ZORBTIVE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of short bowel syndrome (SBS) (ICD-10 Group K90.82) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient is currently on specialized nutritional support (such as a high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)

   If yes, **approve for 4 weeks by GPID or GPI-14 for #1 vial per day (max dose not to exceed 8mg per day).**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - ZORBTIVE** requires the following rule(s) be met for approval:
   A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   C. You are currently on specialized nutritional support (such as a high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)
   D. Request for Zorbtive will NOT be approved for athletic enhancement (to perform better in sports) or anti-aging purposes.

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - ZORBTIVE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of short bowel syndrome (SBS) (ICD-10 Group K90.82)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient been on the medication for a total of 4 weeks?

   If yes, do not approve. [**Note**: The patient should only be approved for one 4-week fill in a lifetime.]
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve by GPID or GPI-14 for the remainder of the 4-week total therapy, with a maximum of 4 weeks of therapy. (Please subtract any previous fills; maximum cumulative approval is for 4 weeks.)**

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOMATROPIN - ZORBTIVE** requires the following rule(s) be met for renewal:
   A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. You have NOT been on the requested medication for a total of 4 weeks

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zorbtive.

REFERENCES

Zorbtive [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; September 2019.

Created: 10/22
Effective: 06/01/25 Client Approval: 05/25 P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, ZOMACTON	02824		GPI-10 (3010002000)	BRAND ≠ ZORBTIVE
	SAIZEN, SAIZEN-SAIZENPREP, SEROSTIM			GPI-10 (3010002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of HIV wasting/cachexia (ICD-10 R64) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist, nutritional support specialist, or infectious disease specialist
   - The patient is on optimized HIV anti-retroviral therapy
   - Alternative causes of wasting (e.g., altered metabolism [metabolic and hormonal abnormalities] including testosterone deficiency or peripheral growth hormone resistance, diarrhea, inadequate energy/caloric intake, malignancies, opportunistic infections) have been ruled out

   If yes, continue to #3.
   If no, continue to #6.

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

3. Does the patient have prolonged non-suppressed HIV viremia (a viral load greater than 200 copies/mL) and meet **ONE** of the following criteria?
   - The patient has a greater than 10% loss of baseline body weight AND either chronic diarrhea or chronic weakness or a fever for at least 30 days
   - The patient has 90% ideal body weight (or body mass index [BMI] less than 18.5 kg/m[2]) AND a greater than 10% weight loss from premorbid maximum over a 12-month period
   - The patient has 90% ideal body weight (or body mass index [BMI] less than 18.5 kg/m[2]) AND a greater than 5% weight loss in the previous 6 months

   If yes, continue to #5.
   If no, continue to #4.

4. Does the patient have suppressed HIV viremia (a viral load less than 200 copies/mL) and meet **ONE** of the following criteria?
   - The patient has a greater than 5% loss of premorbid body weight over 6 months
   - The patient has a greater than 10% loss of premorbid body weight over 12 months
   - The patient has a low BMI (less than 20 kg/m[2]) if objective weight loss is not available

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Has the patient received a total of 48 weeks of cumulative treatment with any somatropin (e.g., Genotropin, Humatrope, Norditropin)?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, **approve for 12 weeks by HICL or GPI-10.**

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

6. Is the request for Serostim?

   If yes, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #7.

7. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - The requested medication will NOT be used concurrently with Increlex (mecasermin)

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
   - The patient's height velocity is less than the 25th percentile for age
   - The patient has a low peak growth hormone (less than 10ng/mL) on two GH stimulation tests OR an insulin-like growth factor 1 (IGF-1) of at least 2 SD below the mean for the same age and gender

   If yes, continue to #18.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have **ONE** of the following diagnoses?
   - Short stature associated with Noonan syndrome (ICD-10 Q87.19)
   - Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (ICD-10 E34.328)

   If yes, continue to #10.
   If no, continue to #11.

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

10. Does the patient meet **ALL** of the following criteria?
    - Therapy is prescribed by or in consultation with an endocrinologist
    - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
    - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
    - The requested medication will NOT be used concurrently with Increlex (mecasermin)

    If yes, continue to #18.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

11. Does the patient have a diagnosis of short stature associated with Turner syndrome (ICD-10 Group Q96) and meet **ALL** of the following criteria?
    - Therapy is prescribed by or in consultation with an endocrinologist
    - Turner syndrome diagnosis was confirmed by chromosomal analysis (karyotyping)
    - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
    - The requested medication will NOT be used concurrently with Increlex (mecasermin)

    If yes, continue to #18.
    If no, continue to #12.

12. Does the patient have a diagnosis of short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1) and meet **ALL** of the following criteria?
    - The patient is 2 years of age or older
    - Therapy is prescribed by or in consultation with an endocrinologist
    - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
    - The patient's height is at least 2 standard deviations (SD) below the mean height for children of the same age and gender
    - The requested medication will NOT be used concurrently with Increlex (mecasermin)

    If yes, continue to #18.
    If no, continue to #13.

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

13. Does the patient have a diagnosis of growth failure secondary to chronic kidney disease (CKD) (ICD-10 R62.52; Group N18) and meet **ALL** of the following criteria?
    - The request is for a pediatric patient
    - Therapy is prescribed by or in consultation with an endocrinologist or nephrologist
    - The patient has not had a renal transplant, or it has been at least one year since renal transplant
    - The patient has persistent growth failure (height below the 10th percentile) AND persistent low height velocity (below the 25th percentile)
    - The requested medication will NOT be used concurrently with Increlex (mecasermin)

    If yes, continue to #18.
    If no, continue to #14.

14. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Therapy is prescribed by or in consultation with an endocrinologist
    - The requested medication will NOT be used concurrently with Increlex (mecasermin)

    If yes, continue to #15.
    If no, continue to #17.

15. Is the patient's GHD caused by a congenital, genetic, or organic disease (e.g., craniopharyngioma [tumor], pituitary hypoplasia, ectopic posterior pituitary, previous cranial irradiation)?

    If yes, continue to #18.
    If no, continue to #16.

16. Is the patient's GHD confirmed by **ONE** of the following growth hormone stimulation tests?
    - Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
    - Glucagon-stimulation test (peak response of 3 ng/mL or less AND the patient's BMI is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND the patient's BMI is greater than 30 kg/m2)
    - Macimorelin test (peak growth hormone of 2.8 ng/mL or less)

    If yes, continue to #18.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

17. Does the patient have a diagnosis of Prader-Willi syndrome (PWS) (ICD-10 Q87.11) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has a confirmed genetic diagnosis of PWS
- The requested medication will NOT be used concurrently with Increlex (mecasermin)

If yes, continue to #18.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

18. Is the request for Genotropin or Norditropin Flexpro?

If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the requested drug.**
If no, continue to #19.

19. Is the request for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton **AND** the patient meets the following criterion?
- The patient had a trial of or contraindication to BOTH of the following preferred agents: Genotropin (somatropin) and Norditropin (somatropin)

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Saizen/Saizenprep, Serostim, Zomacton)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have human immunodeficiency virus (HIV: an immune system disease caused by a virus) with wasting or cachexia (condition of severe weight and muscle loss)
   2. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   3. You have short stature associated with Noonan syndrome (a type of genetic disorder)
   4. You have short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (a type of genetic disorder)
   5. You have short stature associated with Turner syndrome (a type of genetic disorder)
   6. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
   7. You have growth failure secondary to chronic kidney disease (CKD: long-term kidney disease)
   8. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)
   9. You have Prader-Willi syndrome (PWS: a type of genetic disorder)

B. If you have human immunodeficiency virus with wasting or cachexia, approval also requires:
   1. You have NOT received a total of 48 weeks of cumulative treatment with any somatropin (such as Genotropin, Humatrope, Norditropin)
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist, or infectious disease specialist (a doctor who specializes in the treatment of infections)
   3. You are on optimized human immunodeficiency virus (HIV) anti-retroviral therapy (a type of treatment for an immune system disease caused by a virus)
   4. Alternative causes of wasting (such as altered metabolism [metabolic and hormonal abnormalities] including testosterone deficiency or peripheral growth hormone resistance, diarrhea, inadequate energy [caloric] intake, malignancies [tumors], or opportunistic infections [an infection that can occur because of a weakened immune system]) have been ruled out

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You have prolonged non-suppressed human immunodeficiency virus (HIV: an immune system disease caused by a virus) viremia (virus in the blood) (a viral load greater than 200 copies/mL) and meet ONE of the following:
      i. You have a greater than 10% loss of baseline body weight AND either chronic (long-term) diarrhea or chronic weakness or a fever for at least 30 days
      ii. You have 90% ideal body weight (or body mass index [BMI: a tool for evaluating body fat] of less than 18.5 kg/m[2]) AND a greater than 10% weight loss from premorbid maximum (highest weight before onset of disease) over a 12-month period
      iii. You have 90% ideal body weight (or body mass index [BMI: a tool for evaluating body fat] of less than 18.5 kg/m[2]) AND a greater than 5% weight loss in the previous 6 months
   b. You have suppressed human immunodeficiency virus (HIV: an immune system disease caused by a virus) viremia (virus in the blood) (a viral load less than 200 copies/mL) and meet ONE of the following:
      i. You have a greater than 5% loss of premorbid (before onset of disease) body weight over 6 months
      ii. You have a greater than 10% loss of premorbid (before onset of disease) body weight over 12 months
      iii. You have a low body mass index (BMI: a tool for evaluating body fat) (less than 20 kg/m[2]) if objective (measurable) weight loss is not available

C. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, approval also requires:

1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
4. You meet at least ONE of the following:
   a. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
   b. Your height velocity is less than the 25th percentile for your age
   c. You have a low peak growth hormone (less than 10ng/mL) on two growth hormone stimulation tests OR an insulin-like growth factor 1 (IGF-1) of at least 2 standard deviations below the mean for your age and gender
5. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

D. If you have short stature associated with Noonan syndrome OR short stature or growth failure with short stature homeobox-containing gene deficiency, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
3. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
4. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
5. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

E. If you have short stature associated with Turner syndrome, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your Turner syndrome diagnosis was confirmed by chromosomal analysis (karyotyping: a type of genetic test)
3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
5. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

F. If you have short stature born small for gestational age, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (a type of imaging test) of the wrist and hand
4. Your height is at least 2 standard deviations (SD: a measure of variation from the average) below the mean (average) height for children of the same age and gender
5. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
6. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

G. If you have growth failure secondary to chronic kidney disease, approval also requires:
1. You are a pediatric patient
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor) or nephrologist (kidney doctor)
3. You have not had a renal (kidney) transplant, or it has been at least one year since you had a renal (kidney) transplant
4. You have persistent growth failure (height below the 10th percentile) and persistent low height velocity (below the 25th percentile)
5. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
6. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

H. If you are an adult patient with growth hormone deficiency, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. Your growth hormone deficiency is caused by a congenital (at birth), genetic, or organic disease (such as craniopharyngioma [tumor], pituitary hypoplasia [a type of brain condition], ectopic posterior pituitary [a type of brain condition], previous cranial irradiation [radiation to the brain])
   b. Your diagnosis is confirmed by ONE of the following growth hormone stimulation tests (tests that measure the body's ability to produce growth hormone):
      i. Insulin tolerance test (peak growth hormone of 5 ng/mL or less)
      ii. Glucagon-stimulation test (peak response of 3 ng/mL or less AND your body mass index [BMI: a tool for evaluating body fat] is less than 25 kg/m2; OR peak response of 3 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a high pre-test probability; OR peak response of 1 ng/mL or less AND your BMI is between 25 and 30 kg/m2 with a low test probability; OR peak response of 1 ng/mL or less AND your BMI is greater than 30 kg/m2)
      iii. Macimorelin test (peak growth hormone of 2.8 ng/mL or less)
5. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

I. If you have Prader-Willi syndrome, approval also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have a confirmed genetic diagnosis of Prader-Willi syndrome
3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
4. If the request is for Humatrope, Omnitrope, Nutropin AQ, Saizen, or Zomacton, approval also requires:
   a. You have tried or have a contraindication to (harmful for you to use) BOTH of the following preferred medications: Genotropin (somatropin), Norditropin (somatropin)

J. Requests for Serostim will only be approved for human immunodeficiency virus with wasting or cachexia diagnosis

K. The requested medication will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (short height due to unknown cause)

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SOMATROPIN

RENEWAL CRITERIA

1. Is the requested medication being used for **ANY** of the following?
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic short stature (ICD-10 R62.52)

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of HIV with wasting or cachexia (ICD-10 R64) and meet **ALL** of the following criteria?
   - The patient is currently on optimized HIV anti-retroviral therapy
   - The patient has experienced a positive response to treatment (e.g., improvement in BMI or weight, physical improvements such as timed walk or chair rise)

   If yes, continue to #3.
   If no, continue to #4.

3. Has the patient received a total of 48 weeks of cumulative treatment with any somatropin (e.g., Genotropin, Humatrope, Norditropin)?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, **approve for 36 weeks (or up to 48 weeks cumulative lifetime treatment duration) by HICL or GPI-10.**

4. Is the request for Serostim?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

   If no, continue to #5.

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

5. Is the request for a pediatric patient with a diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH) (ICD-10 Group E34.3), and does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand, or the patient has not completed prepubertal growth)
   - The patient has an annual growth velocity of at least 2 cm compared with what was observed from the previous year, OR an annual growth velocity of at least 1 cm compared with what was observed from the previous year for patients who are near the terminal phase of puberty
   - The requested medication will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have **ONE** of the following diagnoses?
   - Short stature associated with Noonan syndrome (ICD-10 Q87.19)
   - Short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (ICD-10 E34.328)
   - Short stature associated with Turner syndrome (ICD-10 Group Q96)
   - Short stature born small for gestational age (SGA) (ICD-10 R62.52; Group P05.1)

   If yes continue to #7.
   If no, continue to #8.

7. Does the patient meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand, or the patient has not completed prepubertal growth)
   - The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year, OR annual growth velocity of at least 1 cm compared with what was observed from the previous year for patients that are near the terminal phase of puberty
   - The requested medication will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of growth failure secondary to chronic kidney disease (CKD) (ICD-10 R62.52; Group N18) and meet **ALL** of the following criteria?
   - The request is for a pediatric patient
   - The patient has not undergone a renal transplantation within the past year
   - The patient has a growth velocity of at least 2 cm compared with what was observed from the previous year, OR annual growth velocity of at least 1 cm compared with what was observed from the previous year for patients that are near the terminal phase of puberty
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand, or the patient has not completed prepubertal growth)
   - The requested medication will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #9.

9. Is the request for an adult patient with a diagnosis of growth hormone deficiency (GHD) (ICD-10 E23.0; Group E34.3), and does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The requested medication will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #10.

10. Does the patient have a diagnosis of Prader-Willi syndrome (PWS) (ICD-10 Q87.11) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an endocrinologist
   - The patient has shown improvement in body composition
   - The requested medication will NOT be used concurrently with Increlex (mecasermin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOMATROPIN (Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Saizen/Saizenprep, Serostim, Zomacton)** requires the following rule(s) be met for renewal:

A. You meet ONE of the following:
   1. You have human immunodeficiency virus (HIV: an immune system disease caused by a virus) with wasting or cachexia (condition of severe weight and muscle loss)
   2. You are a pediatric patient with growth failure due to inadequate secretion (release) of endogenous (produced inside the body) growth hormone (GH)
   3. You have short stature associated with Noonan syndrome (a type of genetic disorder)
   4. You have short stature or growth failure with short stature homeobox-containing gene (SHOX) deficiency (a type of genetic disorder)
   5. You have short stature associated with Turner syndrome (a type of genetic disorder)
   6. You have short stature born small for gestational age (SGA: birth weight is lower than expected for the number of weeks of pregnancy)
   7. You have growth failure secondary to chronic kidney disease (CKD: long-term kidney disease)
   8. You are an adult patient with growth hormone deficiency (GHD: type of hormone disorder with low growth hormone)
   9. You have Prader-Willi syndrome (PWS: a type of genetic disorder)

B. If you have human immunodeficiency virus with wasting or cachexia, renewal also requires:
   1. You have NOT received a total of 48 weeks of treatment with any somatropin (such as Genotropin, Humatrope, Norditropin)
   2. You are currently on optimized human immunodeficiency virus (HIV) anti-retroviral therapy (a type of treatment for an immune system disease caused by a virus)
   3. You have experienced a positive response to treatment (such as improvement in body mass index [BMI: a tool for evaluating body fat] or weight, physical improvements such as timed walk or chair rise)

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

C. If you are a pediatric patient with growth failure due to inadequate secretion of endogenous growth hormone, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand OR you have not completed prepubertal growth)
3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)
4. You meet ONE of the following:
   a. Your annual growth velocity is at least 2 cm compared with what was observed from the previous year
   b. Your annual growth velocity is at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty

D. If you have short stature associated with Noonan syndrome, short stature or growth failure with short stature homeobox-containing gene deficiency, short stature associated with Turner syndrome, OR short stature born small for gestational age, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. Your epiphyses (end part of long bone) are not closed as confirmed by radiograph (a type of imaging test) of the wrist and hand OR you have not completed prepubertal growth
3. Your growth velocity is at least 2 cm compared with what was observed from the previous year OR your annual growth velocity of at least 1 cm compared with what was observed from the previous year if you are near the terminal (end) phase of puberty
4. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)

E. If you have growth failure secondary to chronic kidney disease, renewal also requires:
1. You are a pediatric patient
2. You have note not undergone a renal (kidney) transplantation within the past year
3. You have a growth velocity of at least 2 cm compared with what was observed from the previous year OR annual growth velocity of at least 1 cm compared with what was observed from the previous year for patients that are near the terminal (end) phase of puberty
4. Your epiphyses (end part of long bone) are not closed as confirmed by radiograph (a type of imaging test) of the wrist and hand, or you have not completed prepubertal growth
5. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

F. If you are an adult patient with growth hormone deficiency, renewal also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)

G. If you have Prader-Willi syndrome, renewal also requires:
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
2. You have shown improvement in body composition
3. You will NOT use the requested medication concurrently (at the same time) with Increlex (mecasermin)

H. Requests for Serostim will only be approved for human immunodeficiency virus with wasting or cachexia diagnosis

I. The requested medication will NOT be approved for athletic enhancement (to perform better in sports), anti-aging purposes, or idiopathic short stature (short height due to unknown cause)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, and Zomacton.

REFERENCES

Genotropin [Prescribing Information]. New York, NY: Pharmacia & Upjohn Company LLC; July 2025.
Humatrope [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; November 2023.
Norditropin [Prescribing Information]. Plainsboro, NJ: Novo Nordisk Inc.; July 2025.
Nutropin AQ [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; July 2025.
Omnitrope [Prescribing Information]. Princeton, NJ: Sandoz, Inc.; July 2025.
Saizen [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2020.
Serostim [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2022.
Zomacton [Prescribing Information]. Parisppany, NJ: Ferring Pharmaceuticals Inc.; July 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SONIDEGIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SONIDEGIB PHOSPHATE	ODOMZO	42369		GPI-10 (2137006020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced basal cell carcinoma (BCC) (ICD-10 C44.91, C44.01, C44.41, C44.81; Groups C44.11, C44.21, C44.31, C44.51, C44.61, C44.71) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - This is a recurrence of BCC after the patient had surgery or radiation therapy OR the patient is not a candidate for surgery or radiation therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at end of the guideline.

2. Has the patient obtained **ALL** of the following tests prior to initiating therapy?
   - Baseline serum creatinine kinase (CK) level
   - Baseline serum creatinine level
   - Pregnancy status of females of reproductive potential

   If yes, **approve for 12 months by HICL or GPI 10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SONIDEGIB (Odomzo)** requires the following rule(s) be met for approval:
   A. You have locally advanced basal cell carcinoma (BCC: a type of skin cancer that has spread from where it started to nearby tissue or lymph nodes)
   B. You are 18 years of age or older
   C. This is a recurrence (disease returns) of basal cell carcinoma after surgery or radiation therapy OR you are not a candidate for surgery or radiation therapy
   D. You have obtained ALL of the following tests prior to starting therapy:
      1. Baseline serum creatine kinase (CK: a type of lab test) level
      2. Baseline serum creatinine level (a type of lab test to measure kidney function)
      3. If you are a female of reproductive potential, you have verified your pregnancy status

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SONIDEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Odomzo.

REFERENCES

Odomzo [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corp.; August 2023.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SORAFENIB TOSYLATE	NEXAVAR, SORAFENIB TOSYLATE	33400		GPI-10 (2153306040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (ICD-10 C22.0)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) (ICD-10 C73) **AND** meet the following criterion?
   - The patient's cancer is refractory to radioactive iodine treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SORAFENIB (Nexavar)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
      2. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed with surgery)
      3. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) (a type of thyroid cancer that returns, spreads, or is getting worse that does not fully respond to a type of treatment)

   B. If you have locally recurrent or metastatic, progressive, differentiated thyroid carcinoma, approval also requires:
      1. Your cancer is refractory to radioactive iodine treatment (does not respond to a type of treatment)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SORAFENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Nexavar.

REFERENCES

Nexavar [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc. August 2023.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOTATERCEPT-CSRK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOTATERCEPT-CSRK	WINREVAIR	49475		GPI-10 (4011007020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age and older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient been on background PAH therapy (for at least 3 months) with at least TWO of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 21 days.**
   If no, continue to #4.

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SOTATERCEPT-CSRK

INITIAL CRITERIA (CONTINUED)

4. Is the patient on ONE agent from one of the following drug classes, **AND** has a contraindication or intolerance to ALL of the other drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 21 days.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)
   B. You are 18 years of age and older
   C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

   (Initial denial text continued on next page)

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SOTATERCEPT-CSRK

INITIAL CRITERIA (CONTINUED)

E. You meet ONE of the following:
   1. You have been on background PAH therapy (for at least 3 months) with at least TWO of the following medications from different drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])
   2. You are on ONE medication from one of the following drug classes, AND you have a contraindication to (harmful for you to use) or intolerance (side effect) to ALL of the other drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOTATERCEPT-CSRK

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per 21 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SOTATERCEPT-CSRK (Winrevair)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Winrevair.

REFERENCES

Winrevair [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; March 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/24

Created: 04/24
Client Approval: 06/24

P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOTORASIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOTORASIB	LUMAKRAS	47400		GPI-10 (2153248000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has a KRAS G12C-mutation, as determined by an FDA-approved test
   - The patient has received at least one prior systemic therapy

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **120mg: #8 per day.**
   - **240mg: #4 per day.**
   - **320mg: #3 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lumakras will be used in combination with Vectibix (panitumumab)
   - The patient's cancer has a KRAS G12C-mutation, as determined by an FDA-approved test
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

   If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **120mg: #8 per day.**
   - **240mg: #4 per day.**
   - **320mg: #3 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline

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SOTORASIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SOTORASIB (Lumakras)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes, or has spread to other parts of the body)
   2. Metastatic colorectal cancer (mCRC: a type of digestive tract cancer that has spread to other parts of the body)

B. If you have locally advanced or metastatic non-small cell lung cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer has a KRAS G12C-mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test
   3. You have received at least one prior systemic therapy (treatment that targets the entire body)

C. If you have metastatic colorectal cancer, approval also requires:
   1. You are 18 years of age or older
   2. Lumakras will be used in combination with Vectibix (panitumumab)
   3. Your cancer has a KRAS G12C-mutation (abnormal change in a type of gene), as determined by a Food and Drug Administration (FDA)-approved test
   4. You have received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (types of cancer treatments)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumakras.

REFERENCES

Lumakras [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; January 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPARSENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SPARSENTAN	FILSPARI	48721		GPI-10 (5648306500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is at risk of disease progression
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a biopsy
   - The patient has proteinuria of at least 0.5 g/day
   - The patient has an eGFR of at least 30 mL/min/1.73 m(2)
   - The patient had a trial of or contraindication to at least 12 weeks of treatment with ONE of the following clinical standard of care agents: an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan)

     If yes, **approve for 9 months by HICL or GPI-10 with a quantity limit of #1 per day.**
     If no, continue to #2.

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SPARSENTAN

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of focal segmental glomerulosclerosis (FSGS) (ICD-10 Group N04.1) and meet **ALL** of the following criteria?
   - The patient is 8 years of age or older
   - The patient has proteinuria
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient's diagnosis is confirmed by a renal biopsy
   - The patient has a urine-protein creatinine ratio (UPCR) of at least 1.5 g/g
   - The patient has an eGFR of at least 30 mL/min/1.73 m(2)
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE of the following clinical standard of care agents: an ACE inhibitor (e.g., benazepril, lisinopril), an ARB (e.g., losartan, valsartan)
   - Filspari will NOT be used concurrently with an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan)
   - The patient does NOT have nephrotic syndrome as evidenced by nephrotic range proteinuria (i.e., UPCR of at least 3.0 g/g in adults [18 years of age or older]; UPCR of at least 2.0 g/g in children [less than 18 years of age])
   - The patient does NOT have nephrotic syndrome as evidenced by the presence of hypoalbuminemia, edema, or hyperlipidemia

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPARSENTAN (Filspari)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
      2. Focal segmental glomerulosclerosis (FSGS: a type of kidney disease)

   B. If you have primary immunoglobulin A nephropathy, approval also requires:
      1. You are 18 years of age or older
      2. You are at risk of disease progression (worsening)
      3. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
      4. Your diagnosis is confirmed by a biopsy (removal of cells or tissue for examination)
      5. You have proteinuria (high levels of protein in the urine) of at least 0.5 g/day
      6. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)

   (Initial denial text continued on next page)

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SPARSENTAN

INITIAL CRITERIA (CONTINUED)

7. You have tried or have a contraindication to (harmful for you to use) at least 12 weeks of treatment with ONE of the following clinical standard of care medications: an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)

C. If you have focal segmental glomerulosclerosis, approval also requires:

1. You are 8 years of age or older
2. You have proteinuria (high levels of protein in the urine)
3. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
4. Your diagnosis is confirmed by a renal biopsy (removal of cells or tissue from the kidney for examination)
5. You have a urine-protein creatinine ratio (UPCR: a test that measures the amount of protein in urine) of at least 1.5 g/g
6. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of at least 30 mL/min/1.73 m(2)
7. You have tried or have a contraindication to (harmful for you to use) at least 3 months of treatment with ONE of the following clinical standard of care medications: an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril), an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)
8. You will NOT use Filspari concurrently (at the same time) with an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)
9. You do NOT have nephrotic syndrome (a type of kidney disease) as shown by nephrotic range proteinuria (high levels of protein in the urine) [urine-protein creatinine ratio (UPCR: a test that measures the amount of protein in urine) of at least 3.0 g/g in adults (18 years of age or older); UPCR of at least 2.0 g/g in children (less than 18 years of age)]
10. You do NOT have nephrotic syndrome (a type of kidney disease) as shown by hypoalbuminemia (low levels of protein in the urine), edema (swelling caused by fluid build-up in the body), or hyperlipidemia (high level of fat in the blood)

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SPARSENTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary immunoglobulin A nephropathy (IgAN) (ICD-10 Group N02.B) **AND** meet the following criterion?
   - The patient has improved or stable kidney function compared to baseline OR has a reduction in proteinuria

   If yes, **approve for 9 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of focal segmental glomerulosclerosis (FSGS) (ICD-10 Group N04.1) and meet **ALL** of the following criteria?
   - The patient has had a greater than 40% reduction in proteinuria from baseline
   - The patient has a urine-protein creatinine ratio (UPCR) less than 1.5 g/g
   - Filspari will NOT be used concurrently with an ACE inhibitor (e.g., benazepril, lisinopril) or an ARB (e.g., losartan, valsartan)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPARSENTAN (Filspari)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Primary immunoglobulin A nephropathy (IgAN: a type of kidney disease)
      2. Focal segmental glomerulosclerosis (FSGS: a type of kidney disease)

   B. If you have primary immunoglobulin A nephropathy, renewal also requires:
      1. You have improved or stable kidney function compared to baseline (before starting Filspari) OR you have a reduction (decrease) in proteinuria (a condition with high levels of protein in the urine)

   (Renewal denial text continued on next page)

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SPARSENTAN

RENEWAL CRITERIA (CONTINUED)

C. If you have focal segmental glomerulosclerosis, renewal also requires:

1. You have had a greater than 40% reduction (decrease) in proteinuria (a condition with high levels of protein in the urine) compared to baseline (before starting Filspari)
2. You have a urine-protein creatinine ratio (UPCR: a test that measures the amount of protein in urine) of less than 1.5 g/g
3. You will NOT use Filspari concurrently (at the same time) with an angiotensin converting enzyme inhibitor (ACE-I: a type of medication used to protect kidneys, such as benazepril, lisinopril) or an angiotensin receptor blocker (ARB: a type of medication used to protect kidneys, such as losartan, valsartan)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Filspari.

REFERENCES

Filspari [Prescribing Information]. San Diego, CA: Travere Therapeutics, Inc.; April 2026.

Created: 03/23
Effective: 07/15/26 DMC Approval: 06/30/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPESOLIMAB-SBZO - IV (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SPESOLIMAB-SBZO	SPEVIGO		52851	GPI-14 (90250577702050)	

GUIDELINES FOR USE

1. Is the request for the treatment of a generalized pustular psoriasis (GPP) (ICD-10 L40.1) flare and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient weighs at least 40 kg (88 lbs)
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has sterile, macroscopically visible pustules on non-acral skin
   - The patient has NOT received more than one dose in the previous 30 days and that dose was NOT within the last 7 days
   - Spevigo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPP flare

   If yes, **approve for 1 month by GPID or GPI-14 with a quantity limit of #15 mL for 1 fill.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SPESOLIMAB-SBZO - IV (Spevigo)** requires the following rule(s) be met for approval:
   A. Spevigo will be used for the treatment of a generalized pustular psoriasis (GPP: a type of skin condition) flare
   B. You are 12 years of age or older
   C. You weigh at least 40 kilograms (88 pounds)
   D. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   E. You have sterile, macroscopically visible pustules (blisters with non-infectious pus that can be seen with the naked eye) on non-acral skin (skin in areas of the body such as arms and legs)
   F. You have NOT received more than one dose in the previous 30 days and that dose was NOT within the last 7 days
   G. You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of generalized pustular psoriasis flare

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SPESOLIMAB-SBZO - IV (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spevigo.

REFERENCES

Spevigo [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2024.

Created: 09/22
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPESOLIMAB-SBZO - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SPESOLIMAB-SBZO	SPEVIGO		55498 57703	GPI-14 (9025057770E530, 9025057770E540)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized pustular psoriasis (GPP) (ICD-10 L40.1) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient weighs at least 40 kg (88 lbs)
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has a history of GPP flares of moderate to severe intensity defined as at least 5% body surface area covered with erythema and the presence of pustules AND a Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA] total score of at least 3
   - Spevigo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPP

   If yes, **approve for 3 months by GPID or GPI-14 with a quantity limit of #2mL per 28 days. (Please enter a 1 month approval by GPID or GPI-14 with a quantity limit of #4mL per 28 days for 1 fill.)**

   If no, do not approve.

   INITIAL DENIAL TEXT: Our guideline named **SPESOLIMAB-SBZO - SQ (Spevigo)** requires the following rule(s) be met for approval:
   A. You have generalized pustular psoriasis (GPP: a type of skin condition)
   B. You are 12 years of age or older
   C. You weigh at least 40 kilograms (88 pounds)
   D. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   E. You have a history of generalized pustular psoriasis (GPP: a type of skin condition) flares of moderate to severe intensity defined as at least 5% body surface area (BSA) covered with erythema (a type of skin condition) and the presence of pustules (a type of skin condition) AND a Generalized Pustular Psoriasis Physician Global Assessment [GPPPGA: a tool used to evaluate disease severity] total score of at least 3
   F. You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of generalized pustular psoriasis (GPP: a type of skin condition)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPESOLIMAB-SBZO - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of generalized pustular psoriasis (GPP) (ICD-10 L40.1) and meet **ALL** of the following criteria?
   - The patient has shown a clinical response to therapy
   - Spevigo will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GPP

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **SPESOLIMAB-SBZO - SQ (Spevigo)** requires the following rule(s) be met for renewal:
   A. You have generalized pustular psoriasis (GPP: a type of skin condition)
   B. You have shown a clinical response to therapy
   C. You will NOT use Spevigo concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of generalized pustular psoriasis (GPP: a type of skin condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spevigo.

REFERENCES

Spevigo [Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2025.

Created: 04/24
Effective: 07/15/26 DMC Approval: 07/07/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SPIRONOLACTONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SPIRONOLACTONE	CAROSPIR		15596	GPI-14 (37500020001820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of heart failure (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - The patient has New York Heart Association (NYHA) Class III-IV
   - The patient has a reduced ejection fraction
   - The patient has a contraindication to or is unable to swallow spironolactone tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of hypertension (ICD-10 I10) and meet **ALL** of the following criteria?
   - Carospir will be used as add-on therapy
   - The patient has a contraindication to or is unable to swallow spironolactone tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of edema (ICD-10 Group R60) caused by cirrhosis and meet **ALL** of the following criteria?
   - The patient's edema has not responded to fluid and sodium restrictions
   - The patient has a contraindication to or is unable to swallow spironolactone tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SPIRONOLACTONE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SPIRONOLACTONE (Carospir)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Heart failure (a type of heart condition)
   2. Hypertension (high blood pressure)
   3. Edema (swelling caused by fluid build-up in the body) caused by cirrhosis (liver damage and scarring)

B. If you have heart failure, approval also requires:
   1. You have New York Heart Association (NYHA) Class III-IV (a way to classify severity of heart failure symptoms)
   2. You have a reduced (lower) ejection fraction (amount of blood that the heart can pump out)
   3. You have a contraindication to (harmful for you to use) or are unable to swallow spironolactone tablets

C. If you have hypertension, approval also requires:
   1. Carospir will be used as add-on therapy
   2. You have a contraindication to (harmful for you to use) or are unable to swallow spironolactone tablets

D. If you have edema caused by cirrhosis, approval also requires:
   1. Your edema (swelling caused by fluid build-up in the body) has not responded to fluid and sodium restrictions (limiting the amount of liquids and sodium)
   2. You have a contraindication to (harmful for you to use) or are unable to swallow spironolactone tablets

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Carospir.

REFERENCES

Carospir [Prescribing Information]. Farmville, NC: CMP Pharma, Inc.; August 2023.

Created: 07/25
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

STIRIPENTOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
STIRIPENTOL	DIACOMIT	35461		GPI-10 (7260007000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome (ICD-10 Group G40.83) and meet **ALL** of the following criteria?
   - The patient is 6 months of age or older
   - The patient is currently being treated with clobazam
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to valproic acid or derivatives

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **250mg: #12 per day.**
   - **500mg: #6 per day.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for approval:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You are 6 months of age or older
   C. You are currently being treated with clobazam (a type of seizure medication)
   D. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   E. You have tried or have a contraindication to (harmful for you to use) valproic acid or derivatives

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

STIRIPENTOL

RENEWAL CRITERIA

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome (ICD-10 Group G40.83) **AND** meet the following criterion?
   - The patient is currently being treated with clobazam

   If yes, **approve all formulations of the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **250mg: #12 per day.**
   - **500mg: #6 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for renewal:
   A. You have seizures associated with Dravet syndrome (a rare type of seizure)
   B. You are currently being treated with clobazam (a type of seizure medication)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Diacomit.

REFERENCES

Diacomit [Prescribing Information]. Beauvais, France: Biocodex; July 2022.

Created: 05/19
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUFENTANIL (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUFENTANIL CITRATE	DSUVIA		45928	GPI-14 (65100090100740)	

GUIDELINES FOR USE

1. Does the patient have non-self-administered (NSA) drug benefit coverage?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient have a diagnosis of acute pain and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's pain is severe enough to require an opioid analgesic for which alternative treatments are inadequate (e.g., non-opioid analgesic products or opioid combination products)
   - The patient's treatment center is a Dsuvia Risk Evaluation and Mitigation Strategy (REMS) certified medically supervised healthcare setting, such as a hospital, surgical center, or emergency department

   If yes, **approve for 3 days by GPID or GPI-14 for one fill with a quantity limit of #12 per day.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SUFENTANIL (Dsuvia)** requires the following rule(s) be met for approval:
   A. You have acute pain (sudden and severe pain)
   B. You are 18 years of age or older
   C. Your pain is severe enough to require an opioid analgesic for which alternative treatments are inadequate. Alternative treatments that may be inadequate include non-opioid analgesic products or opioid combination products
   D. Your treatment center is a Dsuvia Risk Evaluation and Mitigation Strategy (REMS) certified medically supervised healthcare setting, such as a hospital, surgical center, or emergency department

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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SUFENTANIL (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dsuvia.

REFERENCES

Dsuvia [Prescribing Information]. Redwood City, CA: AcelRx Pharmaceutical, Inc. October 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/19
Client Approval: 04/20
P&T Approval: 04/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SULOPENEM ETZADROXIL-PROBENECID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SULOPENEM ETZADROXIL-PROBENECID	ORLYNVAH	49961		GPI-10 (1616990275)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of uncomplicated urinary tract infection (uUTI) (ICD-10 N39.0) and meet **ALL** of the following criteria?
   - The patient is a female AND 18 years of age or older
   - The patient's infection is caused by *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis*
   - The patient has limited or no alternative ORAL antibacterial treatment options

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - Therapy is prescribed by or in consultation with an infectious disease (ID) specialist
   - The patient has a documented culture demonstrating uUTI is caused by a bacteria with sensitivity to sulopenem or ertapenem AND resistance or contraindication to all alternatives (e.g. Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP-SMX], nitrofurantoin, fosfomycin, penicillins [e.g., amoxicillin-clavulanate], cephalosporins [e.g., cephalexin], fluoroquinolones [e.g. ciprofloxacin])
   - The request is for continuation of Orlynvah from an inpatient setting

   If yes, **approve for 5 days by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SULOPENEM ETZADROXIL-PROBENECID

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SULOPENEM ETZADROXIL-PROBENECID (Orlynvah)** requires the following rule(s) be met for approval:

A. You have uncomplicated urinary tract infection (uUTI: a type of bacterial infection)
B. You are a female AND 18 years of age or older
C. Your uncomplicated urinary tract infection (a type of bacterial infection) is caused by *Escherichia coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* (types of bacteria)
D. You have limited or no alternative ORAL antibacterial treatment options
E. You meet ONE of the following:
    1. Therapy is prescribed by or in consultation with an infectious disease specialist (a doctor who specializes in the treatment of infections)
    2. You have a documented culture demonstrating your uncomplicated urinary tract infection (a type of bacterial infection) is caused by a bacteria with sensitivity (lab test that shows what medications work on which bacteria) to sulopenem or ertapenem AND resistance (medication will not work for that bacteria) or contraindication (harmful for you to use) to all alternatives (such as Pivya [pivmecillinam], trimethoprim-sulfamethoxazole [TMP- SMX], nitrofurantoin, fosfomycin, penicillins [such as amoxicillin-clavulanate], cephalosporins [such as cephalexin], fluoroquinolones [such as ciprofloxacin])
    3. The request is for continuation of Orlynvah from an inpatient setting

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orlynvah.

REFERENCES

Orlynvah [Prescribing Information]. Chicago, IL: Iterum Therapeutics U.S. Limited; March 2025.

Created: 07/25
Effective: 09/08/25 Client Approval: 08/25 P&T Approval: 10/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUNITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUNITINIB MALATE	SUTENT, SUNITINIB MALATE	33445		GPI-10 (2153307030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST) (ICD-10 Group C49.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to imatinib mesylate (Gleevec)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of unresectable locally advanced or metastatic pancreatic neuroendocrine tumor (pNET) (ICD-10 C25.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is progressive and well-differentiated

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as adjuvant treatment
   - The patient is at high risk of recurrent renal cell carcinoma following nephrectomy

   If yes, **approve for 12 months by HICL or GPI-10, with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See denial text at the end of the guideline.

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SUNITINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SUNITINIB (Sutent)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced renal cell carcinoma (RCC: a type of kidney cancer)
   2. Gastrointestinal stromal tumor (GIST: a type of digestive tumor)
   3. Unresectable locally advanced or metastatic pancreatic neuroendocrine tumor (pNET: a type of tumor in the pancreas that cannot be completely removed by surgery or has spread to other parts of the body)
   4. Renal cell carcinoma

B. If you have advanced renal cell carcinoma, approval also requires:
   1. You are 18 years of age or older

C. If you have gastrointestinal stromal tumor, approval also requires:
   1. You are 18 years of age or older
   2. You have tried or have a contraindication to (harmful for you to use) imatinib mesylate (Gleevec)

D. If you have unresectable locally advanced or metastatic pancreatic neuroendocrine tumor, approval also requires:
   1. You are 18 years of age or older
   2. Your tumor is progressive (getting worse) and well-differentiated (looks like healthy cells)

E. If you have renal cell carcinoma, approval also requires:
   1. You are 18 years of age or older
   2. The requested medication will be used as adjuvant (add-on) treatment
   3. You are at high risk of recurrent renal cell carcinoma (cancer returning) following nephrectomy (surgical removal of kidney)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sutent.

REFERENCES

Sutent [Prescriber Information]. New York, NY. Pfizer, Inc. August 2021.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/18

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUTIMLIMAB-JOME (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUTIMLIMAB-JOME	ENJAYMO	47799		GPI-10 (8580308530)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cold agglutinin disease (CAD) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   Initial request:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #462 mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #308 per 28 days. (Enter a start date of 2 days before the end date of first approval).**

   Subsequent requests:
   - **Approve for 12 months with a quantity limit of #308mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SUTIMLIMAB-JOME (Enjaymo)** requires the following rule(s) be met for approval:
   A. You have cold agglutinin disease (CAD: a rare type of blood condition)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enjaymo.

REFERENCES

Enjaymo [Prescribing Information]. Waltham, MA: Bioverativ USA, Inc.; February 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/24/22
Created: 05/22
Client Approval: 10/22
P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SUZETRIGINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SUZETRIGINE	JOURNAVX	50239		GPI-10 (6417507000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderate to severe acute pain (ICD-10 R52, Group G89.1) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received treatment with Journavx?

   If yes, continue to #3.
   If no, **approve for 30 days by HICL or GPI-10 with a quantity limit of #30 for one fill.**

3. Is the request for the treatment of a new episode of acute pain?

   If yes, **approve for 30 days by HICL or GPI-10 with a quantity limit of #30 for one fill.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **SUZETRIGINE (Journavx)** requires the following rule(s) be met for approval:
   A. You have moderate to severe acute (short-term) pain
   B. You are 18 years of age or older
   C. If you have previously received treatment with Journavx, approval also requires:
      1. The request is for the treatment of a new episode of acute pain

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Journavx.

REFERENCES

Journavx [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals, Inc.; January 2025.

Created: 02/25
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TADALAFIL	CIALIS, TADALAFIL		20736 99409	GPI-14 (40304080000305, 40304080000302)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of benign prostatic hyperplasia (BPH) (ICD-10 Group N40) and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE preferred formulary 5-alpha-reductase inhibitor (e.g., finasteride, dutasteride)
   - The patient had a trial of or contraindication to ONE preferred formulary alpha blocker (e.g., doxazosin, terazosin, tamsulosin, alfuzosin)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength (2.5 mg or 5 mg).**

   If no, continue to #2.

2. Does the patient have a diagnosis of erectile dysfunction (ICD-10 Group N52)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is erectile dysfunction a covered benefit?

   If yes, continue to #4.
   If no, do not approve.
   Change PA type to EX (excluded) and dismiss using the Dismissed letter template.

4. Has the patient tried the preferred agent: generic sildenafil (Viagra)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength (2.5 mg or 5 mg).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TADALAFIL

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TADALAFIL (Cialis)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Benign prostatic hyperplasia (BPH: a type of prostate condition)
   2. Erectile dysfunction (difficulty getting or keeping an erection)

B. If you have benign prostatic hyperplasia, approval also requires:
   1. You have tried or have a contraindication to (harmful for you to use) ONE preferred formulary 5-alpha-reductase inhibitor (such as finasteride, dutasteride)
   2. You have tried or have a contraindication to (harmful for you to use) ONE preferred formulary alpha blocker (such as doxazosin, terazosin, tamsulosin, alfuzosin)

C. **If you have erectile dysfunction, approval also requires**:
   1. You have tried the preferred medication: generic sildenafil (Viagra)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cialis.

REFERENCES

Cialis [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; April 2023.

Created: 11/14
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 01/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-ADCIRCA, ALYQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TADALAFIL	ADCIRCA, ALYQ, TADALAFIL		26587	GPI-14 (40143080000320)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units (WU)

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca, Alyq)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   (Initial denial text continued on the next page)

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TADALAFIL-ADCIRCA, ALYQ

INITIAL CRITERIA (CONTINUED)

C. Your pulmonary arterial hypertension (a type of heart and lung condition) is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   1. Mean pulmonary artery pressure (PAP: a type of measurement) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP: a type of measurement) of 15 mmHg or less
   3. Pulmonary vascular resistance (PVR: a type of measurement) greater than 2 Wood units
D. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
E. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-ADCIRCA, ALYQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - The requested medication will NOT be used concurrently or intermittently with oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (e.g., nitroglycerin, isosorbide mononitrate)
   - The requested medication will NOT be used concurrently with guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca, Alyq)** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   B. You will NOT use the requested medication concurrently (at the same time) or intermittently (off and on) with oral erectile dysfunction medications (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form (such as nitroglycerin, isosorbide mononitrate)
   C. You will NOT use the requested medication concurrently (at the same time) with guanylate cyclase stimulators (such as Adempas [riociguat])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcirca and Alyq.

REFERENCES

Adcirca [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2020.
Alyq [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; April 2023.

Created: 01/08
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAFAMIDIS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAFAMIDIS MEGLUMINE	VYNDAQEL	41631		GPI-10 (4055008020)	
TAFAMIDIS	VYNDAMAX	45729		GPI-10 (4055008000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cardiomyopathy associated with wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
   - The patient has New York Heart Association (NYHA) Class I, II, or III heart failure
   - The requested medication will NOT be used concurrently with a transthyretin stabilizer (acoramidis [Attruby]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of ATTR-CM

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's diagnosis confirmed by **ONE** of the following?
   - A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP *(Note: Strongly positive defined as Grade 2 or 3 uptake using the Perugini Grade 1-3 scoring system)*
   - A biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

   If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
   - **Vyndaqel: #4 per day.**
   - **Vyndamax: #1 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TAFAMIDIS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for approval:

A. You have cardiomyopathy associated with wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
D. You have New York Heart Association (NYHA) Class I, II, or III heart failure (classification of heart failure symptoms)
E. You will NOT use the requested medication concurrently (at the same time) with a transthyretin stabilizer (acoramidis [Attruby]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)
F. Your diagnosis is confirmed by ONE of the following:
    1. A bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging test) (Note: Strongly positive defined as Grade 2 or 3 uptake using the Perugini Grade 1-3 scoring system)
    2. A biopsy of tissue of the affected organ(s) (removal of cells or tissue from the body for examination) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein

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TAFAMIDIS

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cardiomyopathy associated with wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with a transthyretin stabilizer (acoramidis [Attruby]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of ATTR-CM

   If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
   - **Vyndaqel: #4 per day.**
   - **Vyndamax: #1 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for renewal:
   A. You have cardiomyopathy associated with wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
   B. You will NOT use the requested medication concurrently (at the same time) with a transthyretin stabilizer (acoramidis [Attruby]) or transthyretin silencer (vutrisiran [Amvuttra]) for the treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyndaqel and Vyndamax.

REFERENCES

Vyndaqel [Prescribing Information]. New York, NY: Pfizer Inc.; October 2023.
Vyndamax [Prescribing Information]. New York, NY: Pfizer Inc.; October 2023.

Created: 05/19
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAFASITAMAB-CXIX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAFASITAMAB-CXIX	MONJUVI	46758		GPI-10 (2135146720)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of diffuse large B-cell lymphoma (DLBCL) (ICD-10 Group C83.3), not otherwise specified, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The cancer has relapsed or is refractory
   - The patient is not eligible for autologous stem cell transplant (ASCT)
   - Monjuvi will be used in combination with Revlimid (lenalidomide)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of follicular lymphoma (FL) (ICD-10 Group C82) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The cancer has relapsed or is refractory
   - Monjuvi will be used in combination with Revlimid (lenalidomide) and rituximab

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TAFASITAMAB-CXIX (Monjuvi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Diffuse large B-cell lymphoma (DLBCL: a type of blood cancer)
      2. Follicular lymphoma (FL: a type of blood cancer)

   B. If you have diffuse large B-cell lymphoma (not otherwise specified), approval also requires:
      1. You are 18 years of age or older
      2. Your cancer has relapsed or is refractory (cancer that has returned or does not fully respond to treatment)
      3. You are not eligible for autologous stem cell transplant (ASCT: stem cell transplant transferred from your own body)
      4. Monjuvi will be used in combination with Revlimid (lenalidomide)

   (Denial text continued on next page)

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TAFASITAMAB-CXIX

GUIDELINE FOR USE (CONTINUED)

C. If you have follicular lymphoma, approval also requires:
1. You are 18 years of age or older
2. Your cancer has relapsed or is refractory (cancer that has returned or does not fully respond to treatment)
3. Monjuvi will be used in combination with Revlimid (lenalidomide) and rituximab

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Monjuvi.

REFERENCES
Monjuvi [Prescribing Information]. Wilmington, DE: Incyte Corporation; June 2025.

Created: 10/20
Effective: 08/11/25 Client Approval: 07/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAGRAXOFUSP-ERZS (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAGRAXOFUSP-ERZS	ELZONRIS	45555		GPI-10 (2170308030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) **AND** meet the following criterion?
- The patient is 2 years of age or older

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 fill per 21 days.** If no, do not approve.
DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAGRAXOFUSP-ERZS (Elzonris)** requires the following rule(s) be met for approval:
A. You have blastic plasmacytoid dendritic cell neoplasm (BPDCN: aggressive and rare disease of the bone marrow and blood that can affect multiple organs)
B. You are 2 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Elzonris.

REFERENCES
Elzonris [Prescribing Information]. New York, NY: Stemline Therapeutics, Inc., December 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 05/19
Client Approval: 04/20
P&T Approval: 04/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALAZOPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALAZOPARIB TOSYLATE	TALZENNA	45368		GPI-10 (2153558040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's cancer is human epidermal growth factor receptor 2 (HER2)-negative
   - The patient's cancer has a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*), as confirmed by an FDA-approved companion diagnostic test for Talzenna
   - The patient has been treated with chemotherapy (e.g., doxorubicin, docetaxel) in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #2**.**
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer is NOT hormone receptor (HR)-positive
   - The patient's cancer is hormone receptor (HR)-positive, AND the patient has received prior treatment with endocrine therapy (e.g., tamoxifen, Arimidex [anastrozole]) or endocrine therapy is considered to be inappropriate for the patient

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (ICD-10 Z19.2, C61) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Talzenna will be used in combination with Xtandi (enzalutamide)
   - The patient's cancer has a homologous recombination repair (HRR) gene mutation

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TALAZOPARIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Talzenna will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron-Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TALAZOPARIB (TALZENNA)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Locally advanced or metastatic breast cancer (cancer that has spread to nearby tissue or lymph nodes or other parts of the body)
      2. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

   B. If you have locally advanced or metastatic breast cancer, approval also requires:
      1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
      2. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (gBRCAm: a type of abnormal change in a gene), as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic test for Talzenna
      3. You have been treated with chemotherapy (such as doxorubicin, docetaxel) in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
      4. You meet ONE of the following:
         a. You do NOT have hormone receptor (HR: a type of protein)-positive breast cancer
         b. You have hormone receptor (HR)-positive breast cancer, and you have been treated with prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]), or endocrine therapy is considered to be inappropriate for you

   (Denial text continued on next page)

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TALAZOPARIB

GUIDELINES FOR USE (CONTINUED)

C. If you have prostate cancer, approval also requires:

1. You are 18 years of age or older
2. Talzenna will be used in combination with Xtandi (enzalutamide)
3. Your cancer has a homologous recombination repair (HRR) gene mutation (a type of abnormal change in a gene)
4. You meet ONE of the following:
   a. You had a bilateral orchiectomy (both testicles have been surgically removed)
   b. You have a castrate level of testosterone (blood testosterone levels are less than 50 ng/dL)
   c. Talzenna will be used concurrently (at the same time) with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron-Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Talzenna.

REFERENCES

Talzenna [Prescribing Information]. New York, NY: Pfizer Labs; March 2024.

Created: 02/19
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 07/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALETRECTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALETRECTINIB ADIPATE	IBTROZI	50637		GPI-10 (2153387505)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor is ROS1-positive

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TALETRECTINIB (Ibtrozi)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. You are 18 years of age or older
   C. Your tumor is ROS1-positive (abnormal change in a type of gene)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibtrozi.

REFERENCES

Ibtrozi [Prescribing Information]. Burlington, MA: Nuvation Bio Inc.; June 2025.

Created: 06/25
Effective: 08/04/25 Client Approval: 06/25 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALIGLUCERASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALIGLUCERASE ALFA	ELELYSO	38937		GPI-10 (8270008010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease (ICD-10 E75.22) and meet the following criterion?
   - The patient is 4 years of age or older

   If yes, **approve for up to 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TALIGLUCERASE ALFA (Elelyso)** requires the following rule(s) be met for approval:
   A. You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
   B. You are 4 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elelyso.

REFERENCES

Elelyso [Prescribing Information]. New York, NY: Pfizer Labs; December 2025.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALIMOGENE LAHERPAREPVEC

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALIMOGENE LAHERPAREPVEC	IMLYGIC	42741		GPI-10 (2157407040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable melanoma and meet **ALL** of the following criteria?
   - The patient has a recurrence of melanoma lesions after initial surgery
   - The patient does not have a history of primary or acquired immunodeficient states, leukemia, lymphoma, or AIDS
   - The patient is not currently receiving immunosuppressive therapy
   - The patient is not receiving concurrent medical therapy for the treatment of melanoma including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Imlygic be injected into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance?

   If yes, **approve for a total of 12 months and enter three prior authorizations (initial, second, and maintenance doses) by GPID or GPI-14 as follows:**
   - **First authorization: approve for 1 fill of Imlygic 10^6 (1 million) PFU/mL vial: 4mL (#4 vials)**
   - **Second authorization (starting 3 weeks after initial authorization): approve for 1 fill of Imlygic 10^8 (100 million) PFU/mL vial: 4mL (#4 vials)**
   - **Third authorization (starting 5 weeks after initial authorization): approve for 11 months for Imlygic 10^8 (100 million) PFU/mL vial: 8mL (#8 vials) every 28 days**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TALIMOGENE LAHERPAREPVEC

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline for **TALIMOGENE LAHERPAREPVEC (Imlygic)** requires the following rule(s) be met for approval:

A. You have unresectable melanoma (type of skin cancer that cannot be removed with surgery)
B. Your melanoma lesions are recurrent after initial surgery (cancer returns after surgery)
C. You do not have a history of primary or acquired immunodeficient states (conditions that weaken your immune system), leukemia (type of white blood cell cancer), lymphoma (type of cancer affecting immune system), or Acquired Immunodeficiency Syndrome (AIDS)
D. You are not currently receiving immunosuppressive therapy (treatment that weakens your immune system)
E. You are not receiving concurrent medical therapy for the treatment of melanoma including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy
F. The request is for Imlygic to be injected into cutaneous, subcutaneous, and/or nodal lesions (injected into the skin layers) that are visible, palpable (can be felt), or detectable by ultrasound guidance

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imlygic.

REFERENCES

Imlygic [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; October 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/15
Client Approval: 04/20
P&T Approval: 11/15

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALQUETAMAB-TGVS (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALQUETAMAB-TGVS	TALVEY	49135		GPI-10 (2135207680)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least four prior lines of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TALQUETAMAB-TGVS (Talvey)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have received at least four prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (such as Darzalex [daratumumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Talvey.

REFERENCES

Talvey [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 12/01/23
Created: 10/23
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P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAPINAROF

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAPINAROF	VTAMA	48031		GPI-10 (9025007500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient had a trial of or contraindication to **ONE** of the following clinical standard of care agents?
   - High or super-high potency topical corticosteroid (e.g., triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
   - Topical vitamin D analog (e.g., calcipotriene cream, calcitriol ointment)
   - Topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus)
   - Topical retinoid (e.g., tazarotene cream/gel)
   - Anthralin

   If yes, **approve for 3 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TAPINAROF

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to the clinical standard of care agent: a topical corticosteroid (e.g., triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
   - The patient had a trial of or contraindication to the preferred agent: a topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])

   If yes, **approve for 3 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Plaque psoriasis (a type of skin condition)
      2. Atopic dermatitis (a type of skin condition)
   B. If you have plaque psoriasis, approval also requires:
      1. You are 18 years of age or older
      2. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care medications:
         a. High or super-high potency topical corticosteroid (such as triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
         b. Topical vitamin D analog (such as calcipotriene cream, calcitriol ointment)
         c. Topical calcineurin inhibitor (such as tacrolimus, pimecrolimus)
         d. Topical retinoid (such as tazarotene cream/gel)
         e. Anthralin
   C. If you have atopic dermatitis, approval also requires:
      1. You are 2 years of age or older
      2. You meet ONE of the following:
         a. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: a topical corticosteroid (such as triamcinolone 0.1% cream or ointment, mometasone furoate 0.1% ointment, fluocinonide 0.05% cream, halobetasol propionate 0.05% ointment)
         b. You have tried or have a contraindication to (harmful for you to use) the preferred medication: a topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TAPINAROF

RENEWAL CRITERIA

1. Does the patient have a diagnosis of plaque psoriasis (ICD-10 L40.0) **AND** meet the following criterion?
   - The patient has achieved or maintained clear or minimal disease

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient have a diagnosis of atopic dermatitis (ICD-10 Group L20) **AND** meet the following criterion?
   - The patient has experienced or maintained improvement in pruritus, relapsing-remitting dermatitis, or facial/interdigital involvement

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TAPINAROF (Vtama)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Plaque psoriasis (a type of skin condition)
      2. Atopic dermatitis (a type of skin condition)
   B. If you have plaque psoriasis, renewal also requires:
      1. You have achieved or maintained clear or minimal disease
   C. If you have atopic dermatitis, renewal also requires:
      1. You have experienced or maintained improvement in pruritus (itchiness), relapsing-remitting dermatitis (a type of skin condition that returns and goes away), or facial/interdigital (between the fingers or toes) involvement

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vtama.

REFERENCES

Vtama [Prescribing Information]. Long Beach, CA: Dermavant Sciences, Inc.; December 2024.

Created: 05/22
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TARLATAMAB-DLLE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TARLATAMAB-DLLE	IMDELLTRA	49625		GPI-10 (2135207820)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of small cell lung cancer (SCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has extensive-stage (ES) cancer
   - The patient has disease progression during or after platinum-based chemotherapy (e.g., carboplatin, cisplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TARLATAMAB-DLLE (Imdelltra)** requires the following rule(s) be met for approval:
   A. You have small cell lung cancer (SCLC: a type of lung cancer)
   B. You are 18 years of age or older
   C. You have extensive-stage cancer (ES: cancer that has spread widely throughout the lungs or other parts of the body)
   D. You have disease progression (worsening of disease) during or after platinum-based chemotherapy (a type of therapy to treat cancer such as carboplatin, cisplatin)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imdelltra.

REFERENCES

Imdelltra [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; May 2024.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 06/10/24
Created: 05/24
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P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TASIMELTEON

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TASIMELTEON	HETLIOZ, HETLIOZ LQ, TASIMELTEON	40927		GPI-10 (6025007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-24 hour sleep-wake disorder (N24HSWD) (ICD-10 G47.24, G47.9) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is light-insensitive or has total blindness
   - The patient had a trial and failure of maximally-tolerated melatonin therapy
   - The requested medication is for the Hetlioz (tasimelteon) capsules

   If yes, **approve the capsule for a lifetime by GPID or GPI-14 with a quantity limit of #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) (ICD-10 Q93.88) and meet the following criterion?
   - The patient had a trial and failure of maximally-tolerated melatonin therapy

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The requested medication is for brand Hetlioz capsules AND the patient is 16 years of age or older
   - The requested medication is for Hetlioz LQ oral suspension AND the patient is 3 years to 15 years of age

   If yes, **approve the requested medication for a lifetime by GPID or GPI-14 with the following quantity limits:**
   - **Brand Hetlioz capsules: #1 per day.**
   - **Hetlioz LQ oral suspension: #5mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TASIMELTEON

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TASIMELTEON (Hetlioz, Hetlioz LQ)** requires the following rules(s) be met for approval:

A. You have one of the following:
   1. Non-24 hour sleep-wake disorder (N24HSWD: a type of sleep condition)
   2. Nighttime sleep disturbances in Smith-Magenis syndrome (SMS: a type of developmental disorder that causes sleeping problems)

B. If you have non-24 hour sleep-wake disorder, approval also requires:
   1. You are 18 years of age or older
   2. You are light-insensitive (not affected by light) or have total blindness
   3. You have tried and failed maximally-tolerated melatonin therapy
   4. You are requesting the capsule

C. If you have nighttime sleep disturbances in Smith-Magenis syndrome, approval also requires:
   1. You are requesting brand Hetlioz capsules if you are 16 years of age or older
   2. You are requesting Hetlioz LQ oral suspension if you are 3 to 15 years old
   3. You have tried and failed maximally-tolerated melatonin therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Hetlioz/Hetlioz LQ.

REFERENCES

Hetlioz/Hetlioz LQ [Prescribing Information]. Washington, D.C.: Vanda Pharmaceuticals, Inc.; December 2020.

Tasimelteon [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; May 2022.

Library	Commercial	NSA
Yes	Yes	No

Created: 03/14
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 01/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAVABOROLE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAVABOROLE	KERYDIN, TAVABOROLE	41353		GPI-10 (9015608000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) (ICD-10 B35.1) of the toenails?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of diabetes, peripheral vascular disease (PVD), or immunosuppression?

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient have pain surrounding the nail or soft tissue involvement?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient tried or have a contraindication to the preferred agents oral terbinafine OR oral itraconazole, **AND** ciclopirox topical solution?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

5. Are five or less toenails affected?

   If yes, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #10mL per 60 days.**
   If no, **approve for 48 weeks by HICL or GPI-10 with a quantity limit of #10mL per 30 days.**

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TAVABOROLE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAVABOROLE (Kerydin)** requires the following rule(s) be met for approval:

A. You have onychomycosis of the toenails (toenail fungus infection)
B. You meet ONE of the following:
    1. You have diabetes (a disorder with high blood sugar), peripheral vascular disease (PVD: a type of blood disorder), or a suppressed immune system
    2. You have pain surrounding the nail or soft tissue
C. You have tried or have a contraindication to (harmful for you to use) the following preferred medications:
    1. Oral terbinafine OR oral itraconazole
    2. Ciclopirox topical solution

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kerydin.

REFERENCES

Kerydin [Prescribing Information]. Palo Alto, CA: Anacor Pharmaceuticals; October 2020.

Created: 11/14
Effective: 03/18/26 Client Approval: 03/26 P&T Approval: 07/18

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TAZEMETOSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAZEMETOSTAT	TAZVERIK	46312		GPI-10 (2153367520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or locally advanced epithelioid sarcoma (ICD-10 C49.9) and meet **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - The patient is not eligible for complete resection

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (ICD-10 Group C82) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's tumors are positive for an EZH2 mutation as detected by an FDA-approved test AND the patient has received at least 2 prior systemic therapies
   - The patient has no satisfactory alternative treatment options

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TAZEMETOSTAT

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAZEMETOSTAT (Tazverik)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic or locally advanced epithelioid sarcoma (a type of soft tissue cancer that has spread to other parts of the body or has spread from where it started to nearby tissue or lymph nodes)
   2. Relapsed or refractory follicular lymphoma (a type of blood cancer that has returned or did not respond to treatment)

B. If you have metastatic or locally advanced epithelioid sarcoma, approval also requires:
   1. You are 16 years of age or older
   2. You are not eligible for complete resection (surgically removing all of a tissue/organ)

C. If you have relapsed or refractory follicular lymphoma, approval also requires:
   1. You are 18 years or older
   2. You meet ONE of the following:
      a. Your tumors are positive for an EZH2 (type of gene) mutation as detected by a Food and Drug Administration (FDA)-approved test AND you have received at least 2 prior systemic therapies (treatment that targets the entire body)
      b. You have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tazverik.

REFERENCES

Tazverik [Prescribing Information]. Cambridge, MA: Epizyme, Inc.; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/20
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TBO-FILGRASTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TBO-FILGRASTIM	GRANIX	40426		GPI-10 (8240152070)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a non-myeloid malignancy and meet **ALL** of the following criteria?
   - The patient is 1 month of age or older
   - Therapy is prescribed by or in consultation with a hematologist or oncologist
   - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
   - The patient had a trial of or contraindication to the preferred agent: Nivestym

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TBO-FILGRASTIM (Granix)** requires the following rule(s) be met for approval:
   A. You have a non-myeloid malignancy (cancer not affecting bone marrow)
   B. You are 1 month of age or older
   C. Therapy is prescribed by or in consultation with a hematologist (blood specialist) or oncologist (cancer/tumor doctor)
   D. You are receiving myelosuppressive anti-cancer drugs (drugs that decrease bone marrow activity) associated with a significant incidence of severe neutropenia (a type of blood condition) with fever
   E. You had a trial of or contraindication (harmful for) to the preferred medication: Nivestym

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TBO-FILGRASTIM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Granix.

REFERENCES

Granix [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/22
Created: 10/22
Client Approval: 10/22
P&T Approval: 07/21

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEBENTAFUSP-TEBN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEBENTAFUSP-TEBN	KIMMTRAK	47779		GPI-10 (2135208060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic uveal melanoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is HLA-A*02:01-positive

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEBENTAFUSP-TEBN (Kimmtrak)** requires the following rule(s) be met for approval:
   A. You have unresectable or metastatic uveal melanoma (a type of eye cancer that is unable to be removed by surgery or has spread to other parts of the body)
   B. You are 18 years of age or older
   C. You are HLA-A*02:01-positive (a complex of genes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kimmtrak.

REFERENCES

Kimmtrak [Prescribing Information]. Conshohocken, PA: Immunocore Commercial LLC; January 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 05/22
Client Approval: 05/22
P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TECLISTAMAB-CQYV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TECLISTAMAB-CQYV	TECVAYLI	48416		GPI-10 (2135208420)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has received at least one prior line of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), AND Tecvayli will be used in combination with Darzalex Faspro (daratumumab-hyaluronidase-fihj)
   - The patient has received at least four prior lines of therapy, including a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (e.g., Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (e.g., Darzalex [daratumumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TECLISTAMAB-CQYV (Tecvayli)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory multiple myeloma (a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You meet ONE of the following:
      1. You have received at least one prior line of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]) and an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), AND Tecvayli will be used in combination with Darzalex Faspro (daratumumab-hyaluronidase-fihj)
      2. You have received at least four prior lines of therapy, including a proteasome inhibitor (such as Velcade [bortezomib], Kyprolis [carfilzomib]), an immunomodulatory agent (such as Revlimid [lenalidomide], Pomalyst [pomalidomide]), and an anti-CD38 monoclonal antibody (such as Darzalex [daratumumab])

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TECLISTAMAB-CQYV

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tecvayli.

REFERENCES

Tecvayli [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc., March 2026.

Created: 01/23
Effective: 03/18/26 Client Approval: 03/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDIZOLID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEDIZOLID PHOSPHATE	SIVEXTRO	41209		GPI-10 (1623007020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of an acute bacterial skin and skin structure infection (ABSSSI) and meet **ONE** of the following criteria?
   - The request is for continuation of therapy (oral or intravenous)
   - The patient is being transitioned from intravenous Sivextro to oral Sivextro
   - The patient had a trial of, contraindication to, or resistance to generic linezolid tablets

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient weigh at least 35 kilograms (77 pounds)?

   If yes, **approve for 1 month by HICL or GPI-10 with a quantity limit of #6 for 1 fill only.**
   If no, continue to #3.

3. Does the patient weigh between 1 kilogram to 34 kilograms (2.2 pounds to 74.8 pounds) **AND** meet the following criterion?
   - The request is for Sivextro intravenous vial

   If yes, **approve the vial for 1 month by GPID or GPI-14 with a quantity limit of #12 for 1 fill only.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDIZOLID

GUIDELINES FOR USE

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEDIZOLID (Sivextro)** requires the following rule(s) be met for approval:

A. You have an acute bacterial skin and skin structure infection (ABSSSI: a type of skin condition)
B. You meet ONE of the following:
   1. The request is for continuation of therapy of oral or intravenous (IV: injection into the vein) Sivextro
   2. You are being transitioned from IV Sivextro to oral Sivextro
   3. You had a trial of, contraindication to (harmful for you to use), or resistance to (medication no longer works as well) generic linezolid tablets
C. If your weight is between 1 kilogram to 34 kilograms (2.2 pounds to 74.8 pounds), only Sivextro intravenous vial will be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sivextro.

REFERENCES

Sivextro [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; April 2025.

Created: 11/24
Effective: 05/12/25 Client Approval: 04/25 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDUGLUTIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEDUGLUTIDE	GATTEX	39890		GPI-10 (5253307000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of short bowel syndrome (SBS) (ICD-10 Group K90.82) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient is dependent on intravenous parenteral nutrition, defined as requiring parenteral nutrition at least three times per week

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for approval:
   A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. You are 1 year of age or older
   C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   D. You are dependent on parenteral nutrition (administration of nutrition through a vein), defined as requiring parenteral nutrition at least three times per week

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEDUGLUTIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of short bowel syndrome (SBS) (ICD-10 Group K90.82) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The patient has achieved at least a 20 percent reduction in parenteral support compared to baseline
   - The patient has NOT achieved enteral autonomy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEDUGLUTIDE (Gattex)** requires the following rule(s) be met for renewal:
   A. You have short bowel syndrome (SBS: the body cannot absorb fluids and nutrients due to a lack of a functional small intestine)
   B. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions)
   C. You have achieved at least a 20 percent reduction in parenteral support (administration of nutrition through a vein) compared to baseline
   D. You have NOT achieved enteral autonomy (you still need nutrition through a tube)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gattex.

REFERENCES

Gattex [Prescribing Information]. Lexington, MA: Shire-NPS Pharmaceutical; February 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/24
Created: 02/13
Client Approval: 08/24
P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TELISOTUZUMAB VEDOTIN-TLLV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TELISOTUZUMAB VEDOTIN-TLLV	EMRELIS	50574		GPI-10 (2135558060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor has high c-Met protein overexpression (at least 50% of tumor cells with strong [3+] staining), as determined by an FDA-approved test
   - The patient has received a prior systemic therapy (e.g., platinum therapy)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TELISOTUZUMAB VEDOTIN-TLLV (Emrelis)** requires the following rule(s) be met for approval:
   A. You have locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC: a type of lung cancer that has spread from where it started to nearby tissue, lymph nodes, or other parts of the body)
   B. You are 18 years of age or older
   C. Your tumor has high c-Met protein overexpression (at least 50 percent of tumor cells with strong [3+] staining) (too many proteins are made), as determined by a Food and Drug Administration (FDA)-approved test
   D. You have received a prior systemic therapy (such as platinum therapy [a type of therapy to treat cancer])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Emrelis.

REFERENCES
Emrelis [Prescribing Information]. North Chicago, IL: AbbVie Inc.; May 2025.

Created: 05/25
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TELOTRISTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TELOTRISTAT ETIPRATE	XERMELO	44132		GPI-10 (5257007510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of carcinoid syndrome diarrhea (ICD-10 E34.0 and R19.7) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Xermelo will be used in combination with a somatostatin analog (SSA) (e.g., octreotide)
   - Therapy is prescribed by or in consultation with an oncologist or gastroenterologist
   - The patient has been receiving a stable dose of long-acting somatostatin analog (SSA) therapy (e.g., Sandostatin LAR [octreotide], Somatuline Depot [lanreotide]) for at least 3 months
   - The patient's diarrhea is inadequately controlled, as defined by having at least four bowel movements per day, while on somatostatin analog (SSA) therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TELOTRISTAT (Xermelo)** requires the following rule(s) be met for approval:
   A. You have carcinoid syndrome diarrhea (loose stools caused by a type of tumor)
   B. You are 18 years of age or older
   C. You will use Xermelo in combination with a somatostatin analog (SSA) (such as octreotide)
   D. Therapy is prescribed by or in consultation with an oncologist (a type of cancer doctor) or gastroenterologist (doctor who treats digestive conditions)
   E. You have been receiving a stable dose of long-acting somatostatin analog (SSA) therapy (such as Sandostatin LAR [octreotide], Somatuline Depot [lanreotide]) for at least 3 months
   F. You have diarrhea that is inadequately controlled, as defined by having at least four bowel movements per day, while on somatostatin analog (SSA) therapy

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xermelo.

REFERENCES

Xermelo [Prescribing Information]. Deerfield, IL: TerSera Therapeutics, LLC; September 2022.

Created: 03/17
Effective: 01/01/26 Client Approval: 11/25 P&T Approval: 10/25

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STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEMOZOLOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEMOZOLOMIDE	TEMODAR , TEMOZOLOMIDE	20355		GPI-10 (2110407000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Anaplastic astrocytoma (ICD-10 C71.9)
   - Glioblastoma multiforme (ICD-10 C72.9; Group C71)
   - Small cell lung cancer (SCLC) (ICD-10 Group C34)

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents, approve by HICL or GPI-10.**
   - **If the plan does NOT cover NSA agents, approve only Temozolomide PO for all strengths by GPID or GPI-14.**

   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   - Temodar will NOT be used concurrently with an immunosuppressive therapy or a medical therapy for the treatment of melanoma

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents, approve by HICL or GPI-10.**
   - **If the plan does NOT cover NSA agents, approve only Temozolomide PO for all strengths by GPID or GPI-14.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TEMOZOLOMIDE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEMOZOLOMIDE (Temodar)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Anaplastic astrocytoma (a type of brain cancer)
   2. Glioblastoma multiforme (a type of brain or spine cancer)
   3. Small cell lung cancer (SCLC: a type of lung cancer)
   4. Metastatic melanoma (a type of skin cancer that has spread to other parts of the body)

B. If you have metastatic melanoma, approval also requires:
   1. Temodar will NOT be used concurrently (at the same time) with an immunosuppressive therapy (treatment that lowers the activity of the body's immune system) or a medical therapy for the treatment of melanoma

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEMOZOLOMIDE

RENEWAL CRITERIA

NOTE: For the diagnoses of Anaplastic astrocytoma, Glioblastoma multiforme, or Small cell lung cancer (SCLC), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of metastatic melanoma (ICD-10 Group C43) **AND** meet the following criterion?
   - Temodar will NOT be used concurrently with an immunosuppressive therapy or a medical therapy for the treatment of melanoma

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents, approve by HICL or GPI-10.**
   - **If the plan does NOT cover NSA agents, approve only Temozolomide PO for all strengths by GPID or GPI-14.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEMOZOLOMIDE (Temodar)** requires the following rule(s) be met for renewal:
   A. You have metastatic melanoma (a type of skin cancer that has spread to other parts of the body)
   B. Temodar will NOT be used concurrently (at the same time) with an immunosuppressive therapy (treatment that lowers the activity of the body's immune system) or a medical therapy for the treatment of melanoma

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEMOZOLOMIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Temodar.

REFERENCES

Temodar [Prescribing Information]. Rahway, NJ: Merck & Co., Inc.; September 2023.

Library	Commercial	NSA
Yes	Yes	Yes

Created: 02/12
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/22

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEMSIROLIMUS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEMSIROLIMUS	TORISEL	34870		GPI-10 (2153257000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 kits (vials) per month.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEMSIROLIMUS (Torisel)** requires the following rule(s) be met for approval:
   A. You have advanced renal cell carcinoma (RCC: type of kidney cancer).

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Torisel.

REFERENCES

Torisel [Prescribing Information]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; March 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TENAPANOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TENAPANOR HCL	IBSRELA		46915	GPI-10 (5255858010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of irritable bowel syndrome with constipation (IBS-C) (ICD-10 K58.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the preferred agents: Linzess (linaclotide) AND Trulance (plecanatide)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TENAPANOR (Ibsrela)** requires the following rule(s) be met for approval:
   A. You have irritable bowel syndrome with constipation (IBS-C: a type of bowel disease)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) the preferred medications: Linzess (linaclotide) AND Trulance (plecanatide)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ibsrela.

REFERENCES

Ibsrela [Prescribing Information]. Waltham, MA: Ardelyx, Inc.; April 2022.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPLIZUMAB-MZWV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEPLIZUMAB-MZWV	TZIELD	48464		GPI-10 (2752106520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of stage 2 type 1 diabetes (ICD-10 Group E10) and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has at least two positive pancreatic islet cell autoantibodies (e.g., insulin autoantibody, glutamic acid decarboxylase 65 autoantibodies, insulinoma-associated antigen 2 autoantibody)
   - An oral glucose tolerance test (or an alternative method, if oral glucose tolerance test is not available) confirms the patient has dysglycemia without overt hyperglycemia
   - The patient's clinical history does not suggest type 2 diabetes
   - The patient has NOT previously received a 14-dose treatment course

   If yes, **approve for 30 days by HICL or GPI-10 with a quantity limit of #28 mL.**
   If no, continue to #2.

2. Does the patient have a diagnosis of stage 3 type 1 diabetes (ICD-10 Group E10) and meet **ALL** of the following criteria?
   - The patient is 8 to 17 years of age
   - The patient has been recently diagnosed (within the last 8 weeks)
   - The patient has at least one positive pancreatic islet cell autoantibody (e.g., insulin autoantibody, glutamic acid decarboxylase 65 autoantibodies, insulinoma-associated antigen 2 autoantibody)
   - The patient has a peak C-peptide of at least 0.2 pmol/mL on a mixed-meal tolerance test (or an alternative method, if a mixed-meal tolerance test is not available)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TEPLIZUMAB-MZWV

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline named **TEPLIZUMAB-MZWV (Tzield)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Stage 2 type 1 diabetes (an immune disorder with high blood sugar)
   2. Stage 3 type 1 diabetes (an immune disorder with high blood sugar)

B. If you have stage 2 type 1 diabetes, approval also requires:
   1. You are 1 year of age or older
   2. You have at least two positive pancreatic islet autoantibodies (predictors of type 1 diabetes such as insulin autoantibody, glutamic acid decarboxylase 65 autoantibodies, insulinoma-associated antigen 2 autoantibody)
   3. An oral glucose tolerance test (or an alternative method, if oral glucose tolerance test is not available) confirms you have dysglycemia (abnormal blood sugar stability) without overt hyperglycemia (high blood sugar)
   4. Your clinical history does not suggest type 2 diabetes (a disorder with high blood sugar)
   5. You have NOT previously received a 14-dose treatment course

C. If you have stage 3 type 1 diabetes, approval also requires:
   1. You are 8 to 17 years of age
   2. You have been recently diagnosed (within the last 8 weeks)
   3. You have at least one positive pancreatic islet cell autoantibody (a predictor of type 1 diabetes such as insulin autoantibody, glutamic acid decarboxylase 65 autoantibodies, insulinoma-associated antigen 2 autoantibody)
   4. You have a peak C-peptide (a type of protein) of at least 0.2 pmol/mL on a mixed-meal tolerance test (a type of test that measures how the body regulates sugar levels in response to food) (or an alternative method, if a mixed-meal tolerance test is not available)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tzield.

REFERENCES

Tzield [Prescribing Information]. Red Bank, NJ: Provention Bio, Inc.; June 2026.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEPROTUMUMAB-TRBW (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEPROTUMUMAB-TRBW	TEPEZZA	46305		GPI-10 (3019207040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of thyroid eye disease?

   If yes, **approve for 12 months by HICL or GPI-10 for #8 fills per year.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEPROTUMUMAB-TRBW (Tepezza)** requires the following rule(s) be met for approval:
   A. You have thyroid eye disease (a rare condition where the muscles and fatty tissues behind the eye become inflamed, causing the eyes to be pushed forward and bulge outwards)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tepezza.

REFERENCES

Tepezza [Prescribing Information]. Lake Forest, IL: Horizon Therapeutics USA, Inc., January 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERAZOSIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERAZOSIN HCL	TEZRULY	00094		GPI-10 (3620204010)	BRAND = TEZRULY

GUIDELINES FOR USE

1. Does the patient have a diagnosis of benign prostatic hyperplasia (BPH) (ICD-10 Group N40) **AND** meet the following criterion?
- The patient has a contraindication to or is unable to swallow terazosin capsules

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
If no, continue to #2.

2. Does the patient have a diagnosis of hypertension (ICD-10 I10) **AND** meet the following criterion?
- The patient has a contraindication to or is unable to swallow terazosin capsules

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #20mL per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TERAZOSIN (Tezruly)** requires the following rule(s) be met for approval:
A. You have ONE of the following:
   1. Benign prostatic hyperplasia (BPH: a type of prostate condition)
   2. Hypertension (high blood pressure)

B. If you have benign prostatic hyperplasia, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow terazosin capsules

C. If you have hypertension, approval also requires:
   1. You have a contraindication to (harmful for you to use) or are unable to swallow terazosin capsules

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tezruly.

REFERENCES
Tezruly [Prescribing Information]. Baudette, MN: ANI Pharmaceuticals, Inc.; July 2024.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERIFLUNOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERIFLUNOMIDE	AUBAGIO, TERIFLUNOMIDE	39624		GPI-10 (6240407000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (IC-10 G35),to include clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TERIFLUNOMIDE (Aubagio)** requires the following rule(s) be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Aubagio.

REFERENCES

Aubagio [Prescribing Information]. Cambridge, MA: Genzyme Corporation; June 2024.

Library	Commercial	NSA
Yes	Yes	No

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TERIPARATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERIPARATIDE	FORTEO, TERIPARATIDE	24700		GPI-10 (3004407000)	

GUIDELINES FOR USE

1. Is the medication being used for **ONE** of the following diagnoses?
   - Postmenopausal osteoporosis (ICD-10 M81.0, Group M80.0)
   - Primary or hypogonadal osteoporosis in a male patient (ICD-10 M81.0, Group M80.0)
   - Glucocorticoid-induced osteoporosis (ICD-10 M81.8, Group M80.8)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient at high risk for fractures defined as **ONE** of the following?
   - History of osteoporotic (fragility, low trauma) fracture(s)
   - Two or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as Synarel [nafarelin])
   - No prior treatment for osteoporosis, AND a FRAX score of at least 20% for any major fracture OR at least 3% for hip fracture

   If yes, continue to #4.
   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is unable to use oral therapy (upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
   - The patient had a trial of, intolerance to, or a contraindication to a bisphosphonate (e.g., Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TERIPARATIDE

GUIDELINES FOR USE (CONTINUED)

4. Has the patient received a total of 24 months cumulative treatment with Forteo (teriparatide)?

   If yes, continue to #5.
   If no, **approve up to 24 months lifetime cumulative treatment duration by HICL or GPI-10 with a quantity limit of #2.24mL per 28 days.**

5. Does the patient remain at or has returned to having a high risk for fracture?

   If yes, **approve up to 12 months by HICL or GPI-10 with a quantity limit of #2.24mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TERIPARATIDE (Forteo)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Postmenopausal osteoporosis (a type of bone condition)
      2. Primary or hypogonadal (low level of sex hormones) osteoporosis (a type of bone condition) in a male patient
      3. Glucocorticoid (steroid)-induced osteoporosis (a type of bone condition)
   B. You meet ONE of the following (1, 2, or 3):
      1. You are at high risk for fractures defined as ONE of the following:
         a. You have a history of osteoporotic (fragility [weakness], low trauma [injury]) fracture(s) (a type of complete or partial break in a bone)
         b. You have TWO or more risk factors for a fracture (such as a history of multiple recent low trauma fractures, bone mineral density [BMD] T-score [a type of lab test] less than or equal to -2.5, corticosteroid [such as prednisone] use, or use of gonadotropin-releasing hormone [GnRH] analogs [such as Synarel (nafarelin)])
         c. You have had no prior treatment for osteoporosis, AND you have a Fracture Risk Assessment Tool (FRAX: a type of test) score of at least 20 percent for any major fracture OR at least 3 percent for a hip fracture

   (Denial text continued on next page)

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TERIPARATIDE

GUIDELINES FOR USE (CONTINUED)

2. You are unable to use oral therapy due to reasons such as upper gastrointestinal (GI: stomach and intestine) problems (such as unable to tolerate oral medications), lower GI problems (such as unable to absorb oral medications), trouble remembering to take oral medications or coordinating an oral bisphosphonate (such as Fosamax [alendronate]) with other oral medications or your daily routine
3. You have tried, have an intolerance to (side effect), or have a contraindication to (harmful for you to use) a bisphosphonate (such as Fosamax [alendronate], Actonel [risedronate], Boniva [ibandronate])

C. You meet ONE of the following:
1. You have received a total of 24 months or more of treatment with Forteo (teriparatide) AND remain at or have returned to having a high risk for fracture
2. You have received a total of less than 24 months of treatment with Forteo (teriparatide)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Forteo and teriparatide.

REFERENCE

Forteo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; July 2024.
Teriparatide [Prescribing Information]. Morristown, NJ: Alvogen, Inc; November 2023.
Teriparatide [Prescribing Information]. Weston, FL: Apotex Corp.; October 2024.

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TESAMORELIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESAMORELIN ACETATE	EGRIFTA SV, EGRIFTA WR	37268		GPI-10 (3015008510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of HIV (ICD-10 B20) with lipodystrophy (ICD-10 E88.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used for the reduction of excess abdominal fat
   - The patient is currently receiving treatment with a protease inhibitor (PI), PI combination (i.e., saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI), OR an NRTI combination (i.e., zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir)

   If yes, **approve the requested medication for 3 months by GPID or GPI-14 with the following quantity limits:**
   - **Egrifta SV: #1 per day.**
   - **Egrifta WR: #1 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESAMORELIN (Egrifta SV, Egrifta WR)** requires the following rule(s) be met for approval:
   A. You have human immunodeficiency virus (HIV: an immune system disease caused by a virus) with lipodystrophy (abnormal distribution of fat in the body)
   B. You are 18 years of age or older
   C. The requested medication will be used for the reduction of excess abdominal fat
   D. You are currently receiving treatment with a protease inhibitor (PI: a type of medication), PI combination (saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI: a type of medication), OR an NRTI combination (zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESAMORELIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Egrifta.

REFERENCES

Egrifta SV [Prescribing Information]. Montreal, Québec, Canada: Theratechnologies Inc.; February 2024.
Egrifta WR [Prescribing Information]. Montreal, Québec, Canada: Theratechnologies Inc.; March 2025.

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TESTOSTERONE CYPIONATE - AZMIRO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE CYPIONATE	AZMIRO		56456	GPI-14 (2310003010E530)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1)?

   If yes, continue to #2.
   If no, continue to #6.

2. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   - The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient had a trial of or contraindication to the preferred agent: generic testosterone cypionate?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient 40 years of age or older?

   If yes, continue to #5.
   If no, **approve for 12 months by HICL or GPI-10.**

5. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE CYPIONATE - AZMIRO
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TESTOSTERONE CYPIONATE - AZMIRO

INITIAL CRITERIA (CONTINUED)

6. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE CYPIONATE - AZMIRO** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

   B. If you are a male with primary or secondary hypogonadism, approval also requires:
      1. You meet ONE of the following showing you have low testosterone levels:
         a. You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         b. You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
      2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic testosterone cypionate
      3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
         a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
         b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   C. If you have gender dysphoria, approval also requires:
      1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE CYPIONATE - AZMIRO

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10.**

3. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE CYPIONATE - AZMIRO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE CYPIONATE - AZMIRO** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. If you are a male with primary or secondary hypogonadism, renewal also requires:
   1. You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
   2. You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

C. If you have gender dysphoria, renewal also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Azmiro.

REFERENCES

Azmiro [Prescribing Information]. Woburn, MA: Azurity Pharmaceuticals, Inc.; July 2025.

Created: 11/24
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 01/25

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TESTOSTERONE CYPIONATE - DEPO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE, TESTOSTERONE CYPIONATE		10191 10194	GPI-14 (23100030102010, 23100030102015, 23100030102070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1)?

   If yes, continue to #2.
   If no, continue to #5.

2. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   - The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 40 years of age or older?

   If yes, continue to #4.
   If no, **approve all strengths for 12 months by GPID or GPI-14.**

4. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE CYPIONATE - DEPO

INITIAL CRITERIA (CONTINUED)

5. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE CYPIONATE - DEPO (Depo-Testosterone)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

   B. If you are a male with primary or secondary hypogonadism, approval also requires:
      1. You meet ONE of the following showing you have low testosterone levels:
         a. You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
         b. You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
      2. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
         a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
         b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   C. If you have gender dysphoria, approval also requires:
      1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE CYPIONATE - DEPO

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve all strengths for 12 months by GPID or GPI-14.**

3. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve all strengths for 12 months by GPID or GPI-14 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE CYPIONATE - DEPO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE CYPIONATE - DEPO (Depo-Testosterone)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. If you are a male with primary or secondary hypogonadism, renewal also requires:
   1. You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
   2. You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

C. If you have gender dysphoria, renewal also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Depo-Testosterone.

REFERENCES

Depo-Testosterone [Prescribing Information]. New York, NY: Pharmacia & Upjohn Company; June 2025.

Created: 02/23
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 07/22

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TESTOSTERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE	ANDRODERM, ANDROGEL, AXIRON, FORTESTA, NATESTO, STRIANT, TESTIM, VOGELXO, TESTOSTERONE	01403		GPI-10 (2310003000)	ROUTE MISCELL., IMPLANT

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1)?

   If yes, continue to #2.
   If no, continue to #7.

2. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   - The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 40 years of age or older?

   If yes, continue to #4.
   If no, continue to #5.

4. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

5. Is the request for AndroGel 1%, AndroGel 1.62%, Axiron, Testim, or Vogelxo?

   If yes, **approve all strengths of all of the following for 12 months by GPID or GPI-14:**
   - **AndroGel (testosterone)**
   - **Axiron (testosterone)**
   - **Testim (testosterone)**
   - **Vogelxo (testosterone)**

   If no, continue to #6.

6. Is the request for Androderm, Fortesta, Natesto, or Striant, **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to TWO preferred agents: testosterone cypionate and intramuscular testosterone enanthate

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. If you are a male with primary or secondary hypogonadism, approval also requires:
   1. You meet ONE of the following showing you have low testosterone levels:
      a. You have at least two total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
      b. You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
   2. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA
   3. If the request is for Androderm, Fortesta, Natesto, or Striant, you have tried or have a contraindication to (harmful for you to use) TWO preferred medications: testosterone cypionate and intramuscular (injected into the muscle) testosterone enanthate

C. If you have gender dysphoria, approval also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) who meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10.**

3. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. If you are a male with primary or secondary hypogonadism, renewal also requires:
   1. You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
   2. You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

C. If you have gender dysphoria, renewal also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related testosterone formulation.

REFERENCES

Androderm [Prescribing Information]. Madison, NJ: Allergan; May 2020.
Androgel 1% [Prescribing Information]. North Chicago, IL: AbbVie Inc.; July 2025.
Androgel 1.62% [Prescribing Information]. North Chicago, IL: Abbvie Inc.; July 2025.
Axiron [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC.; July 2017.
Fortesta [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals.; July 2025.
Natesto [Prescribing Information]. Regensburg, Germany: Haupt Pharma Amareg GmbH; July 2025.
Striant [Prescribing Information]. Malvern, PA: Actient Pharmaceuticals LLC.; October 2016.
Testim [Prescribing Information]. San Antonio, TX: DPT Laboratories, Ltd.; July 2025.
Vogelxo [Prescribing Information]. Maple Grove, MN: Upsher-Smith Lab., Inc.; July 2025.

Created: 02/01
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 07/22

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TESTOSTERONE ENANTHATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE ENANTHATE	TESTOSTERONE ENANTHATE, XYOSTED	01401		GPI-10 (2310003020)	FDB: ROUTE MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1)?

   If yes, continue to #2.
   If no, continue to #7.

2. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   - The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 40 years of age or older?

   If yes, continue to #4.
   If no, continue to #5.

4. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is the request for generic intramuscular testosterone enanthate 200 mg/mL?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

6. Is the request for Xyosted **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0), not secondary to a pathological disorder, **AND** the patient meets the following criterion?
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #8.

8. Is the request for a female patient with a diagnosis of metastatic breast cancer (ICD-10 Group C50) **AND** the patient meets the following criterion?
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, continue to #9.
   If no, continue to #10.

9. Does the patient meet **ONE** of the following criteria?
   - The patient is postmenopausal
   - The patient is premenopausal, benefitted from an oophorectomy, AND is considered to have a hormone-responsive tumor

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

    If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Delayed puberty not due to a pathological disorder (disease) in a male
   3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
   4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. If you are a male with primary or secondary hypogonadism, approval also requires:
   1. You meet ONE of the following showing you have low testosterone levels:
      a. You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
      b. You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
   2. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA
   3. If the request is for Xyosted, approval also requires:
      a. You are 18 years of age or older

C. If you are a male with delayed puberty not secondary to a pathological disorder, approval also requires:
   1. The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

D. If you are a female with metastatic breast cancer, approval also requires:
   1. You meet ONE of the following:
      a. You are postmenopausal (after menopause)
      b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
   2. The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

(Initial denial text continued on next page)

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TESTOSTERONE ENANTHATE

INITIAL CRITERIA (CONTINUED)

E. If you have gender dysphoria, approval also requires:

1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) and the patient meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10.**

3. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the request for a male patient with a diagnosis of delayed puberty (ICD-10 E30.0), not secondary to a pathological disorder, and the patient meets **ALL** of the following criteria?
   - The patient has NOT received more than two 6-month courses of testosterone replacement therapy
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, **approve for 6 months by GPID or GPI-14.**
   If no, continue to #5.

5. Is the request for a female patient with a diagnosis of metastatic breast cancer (ICD-10 Group C50) **AND** the patient meets the following criterion?
   - The request is for generic intramuscular testosterone enanthate 200 mg/mL

   If yes, continue to #6.
   If no, continue to #7.

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA (CONTINUED)

6. Does the patient meet **ONE** of the following criteria?
   - The patient is postmenopausal
   - The patient is premenopausal, benefitted from an oophorectomy, AND is considered to have a hormone-responsive tumor

   If yes, **approve for 12 months by GPID or GPI-14.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

7. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TESTOSTERONE ENANTHATE (Xyosted)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
      2. Delayed puberty not due to a pathological disorder (disease) in a male
      3. Metastatic breast cancer (cancer that has spread to other parts of the body) in a female
      4. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

   (Renewal denial text continued on next page)

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TESTOSTERONE ENANTHATE

RENEWAL CRITERIA (CONTINUED)

B. If you are a male with primary or secondary hypogonadism, renewal also requires:
1. You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
2. You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
   a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
   b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

C. If you are a male with delayed puberty not secondary to a pathological disorder, renewal also requires:
1. You have NOT received more than two 6-month courses of testosterone replacement therapy
2. The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

D. If you are a female with metastatic breast cancer, renewal also requires:
1. You meet ONE of the following:
   a. You are postmenopausal (after menopause)
   b. You are premenopausal (before menopause), you have benefited from an oophorectomy (surgical removal of the ovaries), and your tumor is hormone-responsive
2. The request is for generic intramuscular (injected into the muscle) testosterone enanthate 200 mg/mL

E. If you have gender dysphoria, renewal also requires:
1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TESTOSTERONE ENANTHATE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related testosterone enanthate/Xyosted.

REFERENCES

Testosterone Enanthate [Prescribing Information]. Berkeley Heights, NJ: Hikma Pharmaceuticals, Inc.; November 2021.
Xyosted [Prescribing Information]. Ewing, NJ: Antares Pharma, Inc.; January 2025.

Created: 02/23
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE UNDECANOATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TESTOSTERONE UNDECANOATE	AVEED, JATENZO, KYZATREX, TLANDO, UNDECATREX	07304		GPI-10 (2310003080)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) **AND** the patient meets the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #2.
   If no, continue to #7.

2. Does the patient meet **ONE** of the following criteria confirming low testosterone levels?
   - The patient has at least TWO total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
   - The patient has a free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient 40 years of age or older?

   If yes, continue to #4.
   If no, continue to #5.

4. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE UNDECANOATE

INITIAL CRITERIA (CONTINUED)

5. Is the request for Jatenzo, Kyzatrex, or Tlando **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to ONE preferred generic agent (e.g., intramuscular testosterone cypionate, intramuscular testosterone enanthate, topical testosterone gel)

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, continue to #6.

6. Is the request for Aveed or Undecatrex **AND** the patient meets the following criterion?
   - The patient had a trial of or contraindication to TWO preferred generic agents (e.g., intramuscular testosterone cypionate, intramuscular testosterone enanthate, topical testosterone gel)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TESTOSTERONE UNDECANOATE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE UNDECANOATE (Aveed, Jatenzo, Kyzatrex, Tlando, Undecatrex)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. If you are a male with primary or secondary hypogonadism, approval also requires:
   1. You are 18 years of age or older
   2. You meet ONE of the following showing you have low testosterone levels:
      a. You have at least TWO total serum (blood) testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions
      b. You have a free serum (blood) testosterone level of less than 5 ng/dL (0.17 nmol/L)
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA
   4. If the request is for Aveed or Undecatrex, you have tried or have a contraindication to (harmful for you to use) TWO preferred generic medications (such as intramuscular [injected into the muscle] testosterone cypionate, intramuscular testosterone enanthate, testosterone gel)
   5. If the request is for Jatenzo, Kyzatrex, or Tlando, you have tried or have a contraindication to (harmful for you to use) ONE preferred generic medication (such as intramuscular [injected into the muscle] testosterone cypionate, intramuscular testosterone enanthate, testosterone gel)

C. If you have gender dysphoria, approval also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

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TESTOSTERONE UNDECANOATE

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) (ICD-10 E29.1) and the patient meets **ALL** of the following criteria?
   - The patient has improved symptoms compared to baseline and tolerance to treatment
   - The patient has yearly lab tests, AND both testosterone and hematocrit levels are NOT above the normal range

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient 40 years of age or older?

   If yes, continue to #3.
   If no, **approve for 12 months by HICL or GPI-10.**

3. Has the patient's prostate specific antigen (PSA) been evaluated within the past 12 months and the patient meets **ONE** of the following criteria?
   - The PSA level is less than or equal to 4 ng/mL
   - The PSA level is greater than 4 ng/mL and the provider attests that the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Is the requested agent for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TESTOSTERONE UNDECANOATE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TESTOSTERONE UNDECANOATE (Aveed, Jatenzo, Kyzatrex, Tlando, Undecatrex)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Primary or secondary male hypogonadism (hypotestosteronism or low testosterone)
   2. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)

B. If you are a male with primary or secondary hypogonadism, renewal also requires:
   1. You have shown improvement in your symptoms compared to baseline (before treatment) and tolerance to treatment
   2. You have yearly lab tests, and your testosterone and hematocrit levels (types of blood tests) are not above the normal range
   3. If you are 40 years of age or older, your prostate specific antigen (PSA: lab result that may indicate prostate cancer) has been evaluated within the past 12 months and you meet ONE of the following:
      a. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is less than or equal to 4 ng/mL
      b. The prostate specific antigen (PSA: lab result that may indicate prostate cancer) level is greater than 4 ng/mL and the benefits of ongoing testosterone replacement therapy outweigh the risks associated with the elevated PSA

C. If you have gender dysphoria, renewal also requires:
   1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for the treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aveed, Jatenzo, Kyzatrex, Tlando, or Undecatrex.

REFERENCES

Aveed [Prescribing Information]. Malvern, PA: Endo USA; July 2025.
Jatenzo [Prescribing Information]. Fort Collins, CO: Tolmar, Inc.; September 2025.
Kyzatrex [Prescribing Information]. Raleigh, NC: Marius Pharmaceuticals; July 2025.
Tlando [Prescribing Information]. Ewing, NJ: Verity Pharmaceuticals, Inc.; July 2025.
Undecatrex [Prescribing Information]. San Antonio, TX: Trifluent Pharma, Inc.; September 2022.

Created: 02/23
Effective: 08/01/26 DMC Approval: 07/21/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TETRABENAZINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TETRABENAZINE	XENAZINE, TETRABENAZINE	07350		GPI-10 (6238007000)	

GUIDELINES FOR USE

1. Is the request for a tetrabenazine dosage that exceeds 50 mg?

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease (ICD-10 G10) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a neurologist or movement disorder specialist
   - The patient has been genotyped for CYP2D6 and is identified as an extensive metabolizer (EM) or intermediate metabolizer (IM) of CYP2D6

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **12.5 mg: #3 per day**
   - **25 mg: #4 per day**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease (ICD-10 G10) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a neurologist or movement disorder specialist

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **12.5 mg: #3 per day**
   - **25 mg: #2 per day**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TETRABENAZINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TETRABENAZINE (Xenazine)** requires the following rule(s) be met for approval:

A. You have chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)
B. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor) or movement disorder specialist
C. If your request is for a tetrabenazine dose that is greater than 50 mg, approval also requires:
    1. You have been genotyped (a type of lab test) for CYP2D6 (a type of enzyme) and you are identified as an extensive metabolizer (EM: normal enzyme activity) or intermediate metabolizer (IM: slower than normal enzyme activity) of CYP2D6

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenazine.

REFERENCES

Xenazine [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals, Inc.; November 2019.

Created: 02/09
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZACAFTOR-IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEZACAFTOR/IVACAFTOR	SYMDEKO	44771		GPI-10 (4530990280)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Symdeko will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient is homozygous for the F508del mutation OR has a responsive mutation in the CFTR gene

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEZACAFTOR-IVACAFTOR (Symdeko)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You are 6 years of age or older
   C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
   D. You will NOT use Symdeko concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   E. You are homozygous (have two copies of the same gene) for the F508del mutation (abnormal change) OR you have a responsive mutation in the CFTR gene (abnormal change in a type of gene that can be treated with Symdeko)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZACAFTOR-IVACAFTOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Symdeko will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TEZACAFTOR-IVACAFTOR (Symdeko)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Symdeko concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Symdeko.

REFERENCES

Symdeko [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; August 2023.

Created: 02/18
Effective: 01/28/25 Client Approval: 01/25 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZEPELUMAB-EKKO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEZEPELUMAB-EKKO	TEZSPIRE	47740		GPI-10 (4460807525)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   - Tezspire will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   - Tezspire will NOT be used concurrently with another systemic biologic (e.g., Xolair [omalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid (e.g., prednisone) burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring a hospitalization or emergency room visit within the past 12 months

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**

   If no, continue to #3.

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TEZEPELUMAB-EKKO

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least **THREE** of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist (SABA) (e.g., albuterol) reliever for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease
   - The patient had a 56-day trial of ONE clinical standard of care agent: an intranasal corticosteroid (e.g., mometasone nasal spray)
   - Tezspire will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids)
   - Tezspire will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**

   If no, do not approve.

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TEZEPELUMAB-EKKO

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Severe asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)

B. If you have severe asthma, approval also requires:
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a doctor specializing in allergy or pulmonary (relating to lungs/breathing) medicine
   3. Tezspire will be used in combination with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis), such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline
   4. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma
   5. You meet ONE of the following:
      a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months
      b. You have experienced at least ONE serious asthma exacerbation (worsening of symptoms) requiring a hospitalization or emergency room visit within the past 12 months
      c. You have poor symptom control despite current therapy as shown by at least THREE of the following within the past 4 weeks:
         i. Daytime asthma symptoms more than twice per week
         ii. Any night waking due to asthma
         iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
         iv. Any activity limitation due to asthma

(Initial denial text continued on next page)

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TEZEPELUMAB-EKKO

INITIAL CRITERIA (CONTINUED)

C. If you have chronic rhinosinusitis with nasal polyps, approval also requires:

1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
3. There is evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera), or sinus computed tomography (CT) scan (a type of imaging test)
4. You have inadequately controlled disease
5. You had a 56-day trial of ONE clinical standard of care medication: an intranasal corticosteroid (such as mometasone nasal spray)
6. Tezspire will be used as add-on maintenance treatment (in conjunction [together] with maintenance intranasal steroids [a type of medication used in the nose])
7. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEZEPELUMAB-EKKO

RENEWAL CRITERIA

1. Does the patient have a diagnosis of severe asthma (ICD-10 Group J45.5) and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) (e.g., beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], a long-acting muscarinic antagonist [e.g., Tudorza (aclidinium), Spiriva (tiotropium), Incruse Ellipta (umeclidinium)], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast], theophylline)
   - Tezspire will NOT be used concurrently with another systemic biologic (e.g., Xolair [omalizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of asthma

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbations from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) (ICD-10 Groups J32 and J33) and meet **ALL** of the following criteria?
   - The patient has shown a clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)
   - Tezspire will NOT be used concurrently with another systemic biologic (e.g., Nucala [mepolizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRSwNP

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TEZEPELUMAB-EKKO

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Severe asthma (a type of lung condition)
   2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus ways with small growths in the nose)

B. If you have severe asthma, renewal also requires:
   1. You will continue to use an inhaled corticosteroid (such as beclomethasone, mometasone, budesonide) AND at least ONE other maintenance medication (taken on a regular basis) such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), a long-acting muscarinic antagonist (such as Tudorza [aclidinium], Spiriva [tiotropium], Incruse Ellipta [umeclidinium]), a leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline
   2. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Xolair [omalizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of asthma
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. You have experienced a decrease in asthma exacerbations (worsening of symptoms) from baseline (before starting Tezspire)
      b. You have decreased your use of rescue medications (such as albuterol)
      c. You have an increase in the percent predicted FEV1 (a type of lung test) from pretreatment baseline (before starting Tezspire)
      d. You have a decrease in the severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. If you have chronic rhinosinusitis with nasal polyps, renewal also requires:
   1. You have shown a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell, size of polyps)
   2. You will NOT use Tezspire concurrently (at the same time) with another systemic biologic (such as Nucala [mepolizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of chronic rhinosinusitis with nasal polyps

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TEZEPELUMAB-EKKO

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tezspire.

REFERENCES
Tezspire [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; October 2025.

Created: 01/22
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

THALIDOMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
THALIDOMIDE	THALOMID	11465		GPI-10 (9939207000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (ICD-10 Group C90.0) **AND** meet the following criterion?
   - Thalomid will be used in combination with dexamethasone

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of erythema nodosum leprosum (ENL) (ICD-10 L52)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of anemia due to myelodysplastic syndrome (ICD-10 D64.9 and Group D46) **AND** meet the following criterion?
   - The patient has been treated for anemia due to myelodysplastic syndrome

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
   If no, continue to #4.

4. Does the patient have a diagnosis of Waldenström's macroglobulinemia (ICD-10 C88.0)?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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THALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **THALIDOMIDE (Thalomid)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Multiple myeloma (a type of blood cancer)
   2. Erythema nodosum leprosum (ENL: a type of immune condition)
   3. Anemia due to myelodysplastic syndrome (a type of blood condition due to blood cancer)
   4. Waldenström's macroglobulinemia (a type of blood cancer)

B. If you have multiple myeloma, approval also requires:
   1. Thalomid will be used in combination with dexamethasone

C. If you have anemia due to myelodysplastic syndrome, approval also requires:
   1. You have been treated for anemia due to myelodysplastic syndrome (a type of blood condition due to blood cancer)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Thalomid.

REFERENCES

Thalomid [Prescribing Information]. Summit, NJ: Celgene Corporation; March 2023.

Created: 08/12
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 08/12

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

THYROTROPIN ALFA (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
THYROTROPIN ALFA	THYROGEN	18855		GPI-10 (9420009010)	

GUIDELINES FOR USE

1. Is the requested medication being used as diagnostic tool for serum thyroglobulin (Tg) testing?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

   If no, continue to #2.

2. Does the patient have a diagnosis of thyroid cancer and meet **ALL** of the following criteria?
   - The requested medication will be used as adjunctive treatment for radioiodine ablation of thyroid tissue remnants
   - The patient does not have metastatic disease

   If yes, **approve for 30 days by HICL or GPI-10 for one fill of #2 vials.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **THYROTROPIN ALFA (Thyrogen)** requires the following rule(s) be met for approval:
   A. You have thyroid cancer
   B. The requested medication will be used as adjunctive (add-on) treatment for radioiodine ablation of thyroid tissue remnants (used to destroy thyroid tissue that is left over after using another treatment)
   C. You do not have metastatic disease (you have no signs of the disease spreading to other parts of the body)

   NOTE: The requested medication is not covered under the pharmacy benefit when used as a diagnostic tool for serum thyroglobulin (Tg) testing. It may be covered under the medical benefit.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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THYROTROPIN ALFA (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Thyrogen.

REFERENCES

Thyrogen [Prescribing Information]. Cambridge, MA: Genzyme Corp.; March 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 11/14/22
Created: 08/13
Client Approval: 10/22
P&T Approval: 08/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TILDRAKIZUMAB-ASMN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TILDRAKIZUMAB-ASMN	ILUMYA	44823		GPI-10 (9025058010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
   - Ilumya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Enbrel (etanercept)
     - Otezla (apremilast)
     - Taltz (ixekizumab)
     - Sotyktu (deucravacitinib)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Icotyde (icotrokinra)

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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TILDRAKIZUMAB-ASMN

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for approval:
   A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   D. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
   E. You will NOT use Ilumya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

   (Initial denial text continued on next page)

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TILDRAKIZUMAB-ASMN

INITIAL CRITERIA (CONTINUED)

F. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   2. Tremfya (guselkumab)
   3. Skyrizi (risankizumab-rzaa)
   4. Enbrel (etanercept)
   5. Otezla (apremilast)
   6. Taltz (ixekizumab)
   7. Sotyktu (deucravacitinib)
   8. Bimzelx (bimekizumab-bkzx)
   9. Adalimumab-ryvk/adalimumab-aaty
   10. Icotyde (icotrokinra)

G. You meet ONE of the following:
   1. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   2. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) AND PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
   3. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TILDRAKIZUMAB-ASMN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   - Ilumya will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Enbrel (etanercept)
     - Otezla (apremilast)
     - Taltz (ixekizumab)
     - Sotyktu (deucravacitinib)
     - Bimzelx (bimekizumab-bkzx)
     - Adalimumab-ryvk/adalimumab-aaty
     - Icotyde (icotrokinra)

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.** If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires the following rule(s) be met for renewal:

     A. You have moderate to severe plaque psoriasis (PsO: a type of skin condition)
     B. You have achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index: a tool for evaluating the severity of psoriasis [a type of skin condition]) of at least 50 percent or more
     C. You will NOT use Ilumya concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

     (Renewal denial text continued on next page)

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TILDRAKIZUMAB-ASMN

RENEWAL CRITERIA (CONTINUED)

D. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   1. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   2. Tremfya (guselkumab)
   3. Skyrizi (risankizumab-rzaa)
   4. Enbrel (etanercept)
   5. Otezla (apremilast)
   6. Taltz (ixekizumab)
   7. Sotyktu (deucravacitinib)
   8. Bimzelx (bimekizumab-bkzx)
   9. Adalimumab-ryvk/adalimumab-aaty
   10. Icotyde (icotrokinra)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ilumya.

REFERENCES

Ilumya [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; December 2025.

Created: 08/18
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TIRZEPATIDE - ZEPBOUND

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TIRZEPATIDE	ZEPBOUND	48014		GPI-10 (6125258000)	BRAND = ZEPBOUND, FORM ≠ VIAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe obstructive sleep apnea (OSA) (ICD-10 G47.33)?

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient obese as defined by **ONE** of the following criteria?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's diagnosis is confirmed by documentation of an Apnea Hypopnea Index/Respiratory Disturbance Index/Respiratory Event Index (AHI/RDI/REI) of at least 15 events per hour that is predominantly obstructive
   - There is physician attestation of active enrollment in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
   - The patient has persistent OSA symptoms despite positive airway pressure (PAP) adherence (at least 4 hours per night on at least 70% of nights) OR there is clinical documentation that the patient is not a candidate for or is intolerant to PAP
   - Zepbound will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

   If yes, **approve for 29 weeks by GPID for all strengths or by GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TIRZEPATIDE - ZEPBOUND

INITIAL CRITERIA (CONTINUED)

4. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Is weight loss or weight management a covered benefit?
   (**NOTE:** If weight loss/weight management is NOT a covered benefit - Denied claim would have this POS message - '*Benefit exclusion if only indicated for weight loss.')*

   If yes, continue to #6.
   If no, do not approve.
   Change PA type to EX (excluded) and dismiss using the Dismissed letter template.

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - There is physician attestation of active enrollment in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
   - Zepbound will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TIRZEPATIDE - ZEPBOUND

INITIAL CRITERIA (CONTINUED)

7. Does the patient meet **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non- alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)

   If yes, **approve for 29 weeks by GPID for all strengths or by GPI-10.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TIRZEPATIDE - ZEPBOUND** requires the following rule(s) be met for approval:

   A. The request is for ONE of the following:
      1. Moderate to severe obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep)
      2. Weight loss or weight management

   (Initial denial text continued on next page)

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TIRZEPATIDE - ZEPBOUND

INITIAL CRITERIA (CONTINUED)

B. If you will use Zepbound for moderate to severe obstructive sleep apnea, approval also requires:

1. You are 18 years of age or older
2. You are obese as defined by ONE of the following:
   a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
   b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
3. Your diagnosis is confirmed by documentation of an Apnea Hypopnea Index/Respiratory Disturbance Index/Respiratory Event Index (AHI/RDI/REI) of at least 15 events per hour that is predominantly obstructive
4. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
5. You have persistent obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep) symptoms despite positive airway pressure (PAP: treatment method for sleep apnea) adherence (at least 4 hours per night on at least 70% of nights) OR there is clinical documentation that you are not a candidate for or are intolerant (side effect) to PAP
6. You will NOT use Zepbound concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])

(Initial denial text continued on next page)

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TIRZEPATIDE - ZEPBOUND

INITIAL CRITERIA (CONTINUED)

C. If you will use Zepbound for weight loss or weight management, approval also requires:

1. You are 18 years of age or older
2. You are actively enrolled in an exercise and caloric reduction program, which may include use of an optional weight loss/behavioral modification program
3. You will NOT use Zepbound concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
4. You meet ONE of the following before starting weight loss therapy:
   a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
   b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
   c. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
   d. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

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TIRZEPATIDE - ZEPBOUND

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe obstructive sleep apnea (OSA) (ICD-10 G47.33) and meet **ALL** of the following criteria?
   - Zepbound will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
   - The patient has achieved or maintained a reduction in Apnea Hypopnea Index/Respiratory Disturbance Index/Respiratory Event Index (AHI/RDI/REI) by at least 15 events per hour or by at least 50%

   If yes, **approve for 12 months by GPID for all strengths or by GPI-10.**
   If no, continue to #2.

2. Is the request for weight loss OR weight management (ICD-10 Group E66)?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

3. Is weight loss or weight management a covered benefit?
   (**NOTE:** If weight loss/weight management is NOT a covered benefit - Denied claim would have this POS message - '*Benefit exclusion if only indicated for weight loss.')*

   If yes, continue to #4.
   If no, do not approve.
   Change PA type to EX (excluded) and dismiss using the Dismissed letter template.

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TIRZEPATIDE - ZEPBOUND

RENEWAL CRITERIA

4. Does the patient meet **ONE** of the following criteria prior to initiating weight loss therapy?
   - The patient has a body mass index (BMI) of at least 30 kg/m(2)
   - The patient is Asian and has a BMI of at least 27.5 kg/m(2)
   - The patient has a BMI of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non-alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)
   - The patient is Asian, has a BMI of at least 25 kg/m(2), AND has at least ONE weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia, cardiovascular disease, coronary artery disease, sleep apnea, knee-osteoarthritis, polycystic ovarian syndrome, non- alcoholic steatohepatitis/non-alcoholic fatty liver disease, asthma, and chronic obstructive pulmonary disease)

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient meet **ALL** of the following criteria?
   - Zepbound will NOT be used concurrently with another GLP-1 receptor agonist (e.g., Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
   - The patient has achieved or maintained at least a 5% weight loss of baseline body weight

   If yes, **approve for 12 months by GPID for all strengths or by GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TIRZEPATIDE - ZEPBOUND

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TIRZEPATIDE - ZEPBOUND** requires the following rule(s) be met for renewal:

A. The request is for ONE of the following:
   1. Moderate to severe obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep)
   2. Weight loss or weight management

B. If you will use Zepbound for moderate to severe obstructive sleep apnea, approval also requires:
   1. You will NOT use Zepbound concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
   2. You have achieved or maintained a reduction in Apnea Hypopnea Index/Respiratory Disturbance Index/Respiratory Event Index (AHI/RDI/REI) by at least 15 events per hour or by at least 50%

C. If you will use Zepbound for weight loss or weight management, approval also requires:
   1. You meet ONE of the following before starting weight loss therapy:
      a. You have a body mass index (BMI: a tool for evaluating body fat) of at least 30 kg/m(2)
      b. You are Asian and have a body mass index (BMI: a tool for evaluating body fat) of at least 27.5 kg/m(2)
      c. You have a body mass index (BMI: a tool for evaluating body fat) of at least 27 kg/m(2) AND at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [inflammation in the liver], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])

(Renewal denial text continued on next page)

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TIRZEPATIDE - ZEPBOUND

RENEWAL CRITERIA (CONTINUED)

   d. You are Asian, have a body mass index (BMI: a tool for evaluating body fat) of at least 25 kg/m(2), AND have at least ONE weight-related comorbidity (disease) (such as hypertension [high blood pressure], type 2 diabetes mellitus [a disorder with high blood sugar], dyslipidemia [abnormal levels of fat], cardiovascular disease [condition of the heart or blood vessels], coronary artery disease [CAD: a type of heart condition], sleep apnea [a type of sleep condition with difficulty breathing], osteoarthritis [a type of joint condition] of the knee[s], polycystic ovarian syndrome [a hormonal disorder], non-alcoholic steatohepatitis/non-alcoholic fatty liver disease [a type of liver disease], asthma [a type of lung condition], and chronic obstructive pulmonary disease [COPD: a type of lung condition])
2. You will NOT use Zepbound concurrently (at the same time) with a GLP-1 receptor agonist (a type of medication such as Victoza [liraglutide], Saxenda [liraglutide], Ozempic [semaglutide], Rybelsus [semaglutide], Byetta [exenatide], Bydureon [exenatide extended-release])
3. You have achieved or maintained at least a 5% weight loss of baseline (before treatment) body weight

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zepbound.

REFERENCES

Zepbound [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; February 2026.

Created: 10/14
Effective: 06/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TISOTUMAB VEDOTIN-TFTV (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TISOTUMAB VEDOTIN-TFTV	TIVDAK	47582		GPI-10 (2135928080)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent or metastatic cervical cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had disease progression on or after chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 21 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it .

   Our guideline named **TISOTUMAB VEDOTIN-TFTV (Tivdak)** requires the following rule(s) be met for approval:
   A. You have recurrent or metastatic (cancer that has returned or spread to other parts of the body) cervical cancer
   B. You are 18 years of age or older
   C. You had disease progression on or after chemotherapy (drugs used to treat cancer)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tivdak.

REFERENCES
Tivdak [Prescribing Information]. Bothell, WA: Seagen, Inc.; September 2021.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective:01/01/22
Created: 10/21
Client Approval: 11/21
P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TIVOZANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TIVOZANIB HCL	FOTIVDA	45740		GPI-10 (2153307625)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC) (ICD-10 Groups C64, C65) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient received two or more prior systemic therapies (e.g., Cabometyx [cabozantinib], Keytruda [pembrolizumab], Opdivo [nivolumab])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #21 per 28 days.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TIVOZANIB (Fotivda)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory advanced renal cell carcinoma (a type of kidney cancer that returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have received two or more systemic therapies (such as Cabometyx [cabozantinib], Keytruda [pembrolizumab], Opdivo [nivolumab])

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fotivda.

REFERENCES

Fotivda [Prescribing Information]. Boston, MA: AVEO Pharmaceuticals, Inc.; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/21
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOBRAMYCIN INHALED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOBRAMYCIN	BETHKIS, TOBRAMYCIN		16122	GPI-14 (07000070002530)	
TOBRAMYCIN IN 0.225% SOD CHLOR	TOBI, TOBRAMYCIN		61551	GPI-14 (07000070002520)	
TOBRAMYCIN	TOBI PODHALER		30025 34461	GPI-14 (07000070000120)	
TOBRAMYCIN/NEBULIZER	KITABIS PAK, TOBRAMYCIN		37569	GPI-14 (07000070002520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient has a lung infection with a gram-negative species (e.g., *Pseudomonas aeruginosa*; *Staphylococcus aureus* is not a gram-negative species)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Bethkis (tobramycin), Tobi (tobramycin) inhalation solution, or Kitabis Pak (tobramycin)?

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 as follows:**
   - **Tobi inhalation solution: #280mL (#56 of 5mL ampules) per 28 days (fill count = 6).**
   - **Bethkis: #224mL (#56 of 4mL ampules) per 28 days (fill count = 6).**
   - **Kitabis Pak: #280mL per 28 days (fill count = 6).**

   If no, continue to #3.

3. Is the request for Tobi Podhaler and the patient meets **ONE** of the following criteria?
   - The patient had a trial and failure of or contraindication to ONE generic inhaled tobramycin product
   - The patient is not able to tolerate the prolonged administration of nebulizers

   If yes, **Tobi Podhaler for 12 months by GPID or GPI-14 with a quantity limit of #224 capsules per 28 days (fill count = 6).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TOBRAMYCIN INHALED

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOBRAMYCIN INHALED (Bethkis, Tobi, Tobi Podhaler, Kitabis Pak)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (a type of lung disoder)
B. You are 6 years of age or older
C. You have a lung infection with a gram-negative species (a type of bacteria such as Pseudomonas aeruginosa)
D. If the request is for Tobi Podhaler, approval also requires ONE of the following:
   1. You have tried or have a contraindication to (harmful for you to use) ONE generic inhaled tobramycin product
   2. You are not able to tolerate the prolonged administration of nebulizers

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tobi, Tobi Podhaler, Bethkis or Kitabis.

REFERENCES

Tobi [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2023.
Tobi Podhaler [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2023.
Bethkis [Prescribing Information]. Woodstock, IL: Chiesi USA, Inc.; February 2023.
Kitabis Pak [Prescribing Information]. Midothian, VA: PARI Respiratory Equipment, Inc.; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/12
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB	ACTEMRA		27366 27367 27368	GPI-14 (66500070002030, 66500070002035, 66500070002040)	

PAC NOTE: For requests for the SQ dosage form of Actemra, please see the TOCILIZUMAB-SQ PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized patient?

   If yes, do not approve. [NOTE: This indication is for hospital use only.]
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR/XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #40mL per 28 days.**

   If no, continue to #3.

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Rinvoq (upadacitinib)
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #30mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #5.

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   - The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
     If no, continue to #6.

6. Does the patient have a diagnosis of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) (ICD-10 Group D89.83; Z92.850) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRS

     If yes, **approve for 1 fill by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #160mL.**
     CLINICAL PHARMACISTS: Patient must also meet all criteria in Kymriah guideline to be approvable for both agents.

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB - IV (Actemra - intravenous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
   5. Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS: a type of inflammatory response)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

C. If you have giant cell arteritis, approval also requires:
1. You are 18 years of age or older
2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Rinvoq (upadacitinib)
   b. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

D. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])
   e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

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TOCILIZUMAB - IV

INITIAL CRITERIA (CONTINUED)

E. If you have systemic juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)

F. If you have chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome, approval also requires:
1. You are 2 years of age or older
2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of cytokine release syndrome (a type of inflammatory response)

G. **NOTE:** Actemra will NOT be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized patients.

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB - IV

RENEWAL CRITERIA

NOTE: For the diagnosis of cytokine release syndrome (CRS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR/XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #40mL per 28 days.**

     If no, continue to #2.

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TOCILIZUMAB - IV

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Rinvoq (upadacitinib)
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #30mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #4.

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TOCILIZUMAB - IV

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   - The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, continue to #5.
     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

     If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.**
     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOCILIZUMAB - IV

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB - IV (Actemra - intravenous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

C. If you have giant cell arteritis, renewal also requires:
   1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Rinvoq (upadacitinib)
      b. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

(Renewal denial text continued on next page)

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TOCILIZUMAB - IV

RENEWAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])
   e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

E. If you have systemic juvenile idiopathic arthritis, renewal also requires:
1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)
3. You meet ONE of the following:
   a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB - IV

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Actemra.

REFERENCE
Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2026.

Created: 02/10
Effective: 07/01/26 Client Approval: 06/26 DMC Approval: 06/16/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB	ACTEMRA		35486 45082	GPI-14 (6650007000E520, 6650007000D520)	

PAC NOTE: For requests for the IV dosage form of Actemra, please see the TOCILIZUMAB - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR/XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #2.

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - o Rinvoq (upadacitinib)
     - o Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #3.

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a diagnosis of systemic sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) (e.g., heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors], recurrent aspiration [such as from GERD], pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease [MCTD])
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

     If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #4.

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   - The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB - SQ (Actemra - subcutaneous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to THREE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

C. If you have giant cell arteritis, approval also requires:
1. You are 18 years of age or older
2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Rinvoq (upadacitinib)
   b. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

D. If you have systemic sclerosis-associated interstitial lung disease, approval also requires:
1. You are 18 years of age or older
2. Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
4. You do not have other causes of interstitial lung disease (such as heart failure or fluid overload, drug-induced lung toxicity [lung damage due to side effects of medications such as cyclophosphamide, methotrexate, angiotensin-converting enzyme (ACE)-inhibitors (a type of blood pressure medication)], recurrent aspiration [something enters the airways accidentally] such as from gastroesophageal reflux disease [GERD: acid reflux], pulmonary vascular disease [a condition affecting blood vessels in the lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in the lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease)
5. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

E. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])
   e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

F. If you have systemic juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR/XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Rinvoq (upadacitinib)
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #3.

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RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline
   - Actemra will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to THREE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - Actemra will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA
   - The patient had a trial of or contraindication to the preferred agent: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, continue to #6.
     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

     If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

     If no, do not approve.

     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **TOCILIZUMAB - SQ (Actemra - subcutaneous)** requires the following rule(s) be met for renewal:
     A. You have ONE of the following:
        1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
        2. Giant cell arteritis (GCA: a type of inflammatory condition)
        3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
        4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
        5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

     (Renewal denial text continued on next page)

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Rinvoq, or Xeljanz IR/XR)

C. If you have giant cell arteritis, renewal also requires:
1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Rinvoq (upadacitinib)
   b. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Rinvoq)

D. If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:
1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

E. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) THREE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])
   e. Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh) (**NOTE:** Tyenne and Avtozma require additional step through Enbrel, adalimumab-ryvk/adalimumab-aaty, Xeljanz IR, or Rinvoq)

F. If you have systemic juvenile idiopathic arthritis, renewal also requires:
1. You will NOT use Actemra concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
2. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: Tyenne (tocilizumab-aazg)/Avtozma (tocilizumab-anoh)
3. You meet ONE of the following:
   a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB - SQ

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Actemra.

REFERENCE
Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2025.

Created: 11/13
Effective: 07/01/26 Client Approval: 06/26 DMC Approval: 06/16/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB-AAZG - IV

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB-AAZG	TYENNE		55366 55368 55372	GPI-14 (66500070172030, 66500070172035, 66500070172040)	

PAC NOTE: For requests for the SQ dosage form of Tyenne, please see the TOCILIZUMAB-AAZG-SQ PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized patient?

   If yes, do not approve. [NOTE: This indication is for hospital use only.]
   DENIAL TEXT: See the initial denial text at the end of the guideline.

   If no, continue to #2.

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TOCILIZUMAB-AAZG - IV

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR/XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #40mL per 28 days.**

   If no, continue to #3.

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TOCILIZUMAB-AAZG - IV

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to the preferred agent: Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #30mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #6.

6. Does the patient have a diagnosis of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) (ICD-10 Group D89.83; Z92.850) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CRS

   If yes, **approve for 1 fill by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #160mL.**
   CLINICAL PHARMACISTS: Patient must also meet all criteria in Kymriah guideline to be approvable for both agents.

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB-AAZG - IV (Tyenne - intravenous)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Giant cell arteritis (GCA: a type of inflammatory condition)
      3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)
      5. Chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS: a type of inflammatory response)

   (Initial denial text continued on next page)

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TOCILIZUMAB-AAZG - IV

INITIAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
4. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
5. You have tried or have a contraindication to ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

C. If you have giant cell arteritis, approval also requires:
1. You are 18 years of age or older
2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

(Initial denial text continued on next page)

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INITIAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])

E. If you have systemic juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)

F. If you have chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome, approval also requires:
1. You are 2 years of age or older
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of cytokine release syndrome (a type of inflammatory response)

G. **NOTE:** Tyenne will NOT be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized patients.

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB-AAZG - IV

RENEWAL CRITERIA

NOTE: For the diagnosis of cytokine release syndrome (CRS), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR/XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #40mL per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to the preferred agent: Rinvoq (upadacitinib)

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation with a quantity limit of #30mL per 28 days.**

   If no, continue to #3.

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RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, continue to #4.

4. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) **AND** meet the following criterion?
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths of the IV formulation.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOCILIZUMAB-AAZG - IV

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB-AAZG - IV (Tyenne - intravenous)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   4. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

C. If you have giant cell arteritis, renewal also requires:
   1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
   2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

(Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

D. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])

E. If you have systemic juvenile idiopathic arthritis, renewal also requires:
1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
2. You meet ONE of the following:
   a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB-AAZG - IV

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyenne.

REFERENCE
Tyenne [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; May 2025.
Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2025.

Created: 08/24
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB-AAZG - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB-AAZG	TYENNE		55373 55374	GPI-14 (6650007017D520, 6650007017E520)	

PAC NOTE: For requests for the IV dosage form of Tyenne, please see the TOCILIZUMAB-AAZG - IV PA guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR/XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days. (NOTE: Enter a proactive PA for Avtozma for all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.)**

   If no, continue to #2.

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TOCILIZUMAB-AAZG - SQ

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to the preferred agent: Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days. (NOTE: Enter a proactive PA for Avtozma for all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.)**

   If no, continue to #3.

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a diagnosis of systemic sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) (e.g., heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors], recurrent aspiration [such as from GERD], pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease [MCTD])
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days. (NOTE: Enter a proactive PA for Avtozma for all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.)**

   If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days. (NOTE: Enter a proactive PA for Avtozma for all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days.)**

   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, **approve all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days. (NOTE: Enter a proactive PA for Avtozma for all formulations of the 162mg/0.9mL strength for 6 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB-AAZG - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB-AAZG - SQ (Tyenne - subcutaneous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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INITIAL CRITERIA (CONTINUED)

C. If you have giant cell arteritis, approval also requires:
1. You are 18 years of age or older
2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

D. If you have systemic sclerosis-associated interstitial lung disease, approval also requires:
1. You are 18 years of age or older
2. Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
4. You do not have other causes of interstitial lung disease (such as heart failure or fluid overload, drug-induced lung toxicity [lung damage due to side effects of medications such as cyclophosphamide, methotrexate, angiotensin-converting enzyme (ACE)-inhibitors (a type of blood pressure medication)], recurrent aspiration [something enters the airways accidentally] such as from gastroesophageal reflux disease [GERD: acid reflux], pulmonary vascular disease [a condition affecting blood vessels in the lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in the lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease)
5. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

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INITIAL CRITERIA (CONTINUED)

E. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])

F. If you have systemic juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB-AAZG - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR/XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to the preferred agent: Rinvoq (upadacitinib)

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #3.

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RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline
   - Tyenne will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

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TOCILIZUMAB-AAZG - SQ

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) **AND** meet the following criterion?
   - Tyenne will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

   If yes, **approve all formulations of the 162mg/0.9mL strength for 12 months by GPID or GPI-14 with a quantity limit of #3.6mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB-AAZG - SQ (Tyenne - subcutaneous)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Giant cell arteritis (GCA: a type of inflammatory condition)
      3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
      4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

C. If you have giant cell arteritis, renewal also requires:
1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

D. If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:
1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

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RENEWAL CRITERIA (CONTINUED)

E. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])

F. If you have systemic juvenile idiopathic arthritis, renewal also requires:
1. You will NOT use Tyenne concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
2. You meet ONE of the following:
   a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB-AAZG - SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyenne and Actemra.

REFERENCE

Tyenne [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; May 2025.
Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2025.

Created: 08/24
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB-ANOH - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB-ANOH	AVTOZMA		57009, 57012	GPI-14 (6650007018E520, 6650007018D520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Avtozma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR/XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #2.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
   - Avtozma will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to the preferred agent: Rinvoq (upadacitinib) [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a diagnosis of systemic sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) (e.g., heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors], recurrent aspiration [such as from GERD], pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease [MCTD])
   - Avtozma will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

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TOCILIZUMAB-ANOH - SQ

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Avtozma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - Avtozma will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3.6mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB-ANOH - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOCILIZUMAB-ANOH - SQ (Avtozma - subcutaneous)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Giant cell arteritis (GCA: a type of inflammatory condition)
   3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
   4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
   5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You have tried or have a contraindication to ONE of the following preferred medications:
      a. Enbrel (etanercept)
      b. Adalimumab-ryvk/adalimumab-aaty
      c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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TOCILIZUMAB-ANOH - SQ

INITIAL CRITERIA (CONTINUED)

C. If you have giant cell arteritis, approval also requires:
1. You are 18 years of age or older
2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
3. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
4. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

D. If you have systemic sclerosis-associated interstitial lung disease, approval also requires:
1. You are 18 years of age or older
2. Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
4. You do not have other causes of interstitial lung disease (such as heart failure or fluid overload, drug-induced lung toxicity [lung damage due to side effects of medications such as cyclophosphamide, methotrexate, angiotensin-converting enzyme (ACE)-inhibitors (a type of blood pressure medication)], recurrent aspiration [something enters the airways accidentally] such as from gastroesophageal reflux disease [GERD: acid reflux], pulmonary vascular disease [a condition affecting blood vessels in the lungs], pulmonary edema [excess fluid in the lungs], pneumonia [type of lung infection], chronic pulmonary thromboembolism [blood clot in the lungs], alveolar hemorrhage [bleeding of a part of the lungs], interstitial lung disease caused by another rheumatic [inflammatory] disease such as mixed connective tissue disease)
5. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

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TOCILIZUMAB-ANOH - SQ

INITIAL CRITERIA (CONTINUED)

E. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])

F. If you have systemic juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB-ANOH - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Avtozma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Xeljanz (tofacitinib IR/XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
   - Avtozma will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of GCA
   - The patient had a trial of or contraindication to the preferred agent: Rinvoq (upadacitinib)

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #3.

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RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (ICD-10 M34.81) and meet **ALL** of the following criteria?
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline
   - Avtozma will NOT be used concurrently with another systemic biologic or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SSc-ILD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Avtozma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of PJIA
   - The patient had a trial of or contraindication to ONE of the following preferred agents:
     - Enbrel (etanercept)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

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TOCILIZUMAB-ANOH - SQ

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) (ICD-10 Group M08.2) **AND** meet the following criterion?
   - Avtozma will NOT be used concurrently with another systemic biologic (e.g., Ilaris [canakinumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of SJIA

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient has maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3.6mL per 28 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB-ANOH - SQ (Avtozma - subcutaneous)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
      2. Giant cell arteritis (GCA: a type of inflammatory condition)
      3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: a type of lung condition)
      4. Polyarticular juvenile idiopathic arthritis (PJIA: a type of joint condition)
      5. Systemic juvenile idiopathic arthritis (SJIA: a type of joint condition)

   (Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Xeljanz (tofacitinib immediate release or extended release) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

C. If you have giant cell arteritis, renewal also requires:
1. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Rinvoq (upadacitinib)

D. If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:
1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline
2. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic sclerosis-associated interstitial lung disease (a type of lung condition)

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TOCILIZUMAB-ANOH - SQ

RENEWAL CRITERIA (CONTINUED)

E. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
3. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications:
   a. Enbrel (etanercept)
   b. Adalimumab-ryvk/adalimumab-aaty
   c. Xeljanz IR (tofacitinib immediate release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
   d. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])

F. If you have systemic juvenile idiopathic arthritis, renewal also requires:
1. You will NOT use Avtozma concurrently (at the same time) with another systemic biologic (such as Ilaris [canakinumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of systemic juvenile idiopathic arthritis (a type of joint condition)
2. You meet ONE of the following:
   a. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   b. You have maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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TOCILIZUMAB-ANOH - SQ

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Avtozma and Actemra.

REFERENCE

Avtozma [Prescribing Information]. Jersey City, NJ: CELLTRION USA, Inc.; January 2026.
Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2025.

Created: 06/26
Effective: 07/01/26 Client Approval: 06/26 DMC Approval: 06/16/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR, TOFACITINIB CITRATE, TOFACITINIB CITRATE ER	39768		GPI-10 (6660306510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to at least 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   - **5mg: #2 per day.**
   - **11mg: #1 per day.**

   If no, continue to #2.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
- The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Enbrel [etanercept])

If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
- **5mg: #2 per day.**
- **11mg: #1 per day.**
- **1mg/mL: #10mL per day.**

If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a rheumatologist
- The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS
- The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac)
- The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
- **5mg: #2 per day.**
- **11mg: #1 per day.**

If no, continue to #4.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., adalimumab-ryvk/adalimumab-aaty)

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   - **5mg and 10mg: #2 per day.**
   - **11mg and 22mg: #1 per day.**

   If no, continue to #5.

5. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pcJIA
   - The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

   If yes, **approve for 6 months by GPID or GPI-14 for all of the following:**
   - **5mg: #2 per day.**
   - **1mg/mL: #10mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

C. If you have psoriatic arthritis, approval also requires:
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
   4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Enbrel [etanercept])

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TOFACITINIB

INITIAL CRITERIA (CONTINUED)

D. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam, diclofenac)
5. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty)

F. If you have polyarticular course juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of polyarticular course juvenile idiopathic arthritis (a type of joint condition)
4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

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TOFACITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **5mg: #2 per day.**
   - **11mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **5mg: #2 per day.**
   - **11mg: #1 per day.**
   - **1mg/mL: #10mL per day.**

   If no, continue to #3.

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **5mg: #2 per day.**
   - **11mg: #1 per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **5mg and 10mg: #2 per day.**
   - **11mg and 22mg: #1 per day.**

   If no, continue to #5.

5. Does the patient have a diagnosis of polyarticular course juvenile idiopathic arthritis (pcJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of pcJIA

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **5mg: #2 per day.**
   - **1mg/mL: #10mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Ankylosing spondylitis (AS: a type of joint condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Polyarticular course juvenile idiopathic arthritis (pcJIA: a type of joint condition)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

C. If you have psoriatic arthritis, renewal also requires:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. **If you have ankylosing spondylitis, renewal also requires**:
   1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) score while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

(Renewal denial text continued on next page)

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TOFACITINIB

RENEWAL CRITERIA (CONTINUED)

E. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

F. If you have polyarticular course juvenile idiopathic arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of polyarticular course juvenile idiopathic arthritis (a type of joint condition)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xeljanz/Xeljanz XR.

REFERENCES
Xeljanz, Xeljanz XR [Prescribing Information]. New York, NY: Pfizer Inc.; March 2026.

Created: 11/12
Effective: 07/01/26 Client Approval: 06/26 DMC Approval: 06/09/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOFERSEN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOFERSEN	QALSODY	48878		GPI-10 (7450408000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a superoxide dismutase 1 (SOD1) gene mutation

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   INITIAL REQUESTS: Please enter two authorizations as follows:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #30mL per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #15mL per 28 days (Please enter a start date of 3 days before the end of the first approval).**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #15mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOFERSEN (QALSODY)** requires the following rule(s) be met for approval:
   A. You have amyotrophic lateral sclerosis (ALS: a type of brain and nerve condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor)
   D. You have a superoxide dismutase 1 (SOD1: an enzyme) gene mutation (an abnormal change in your gene)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOFERSEN (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qalsody.

REFERENCES

Qalsody [Prescribing Information]. Cambridge, MA: Biogen MA Inc.; April 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 05/23
Client Approval: 08/23
P&T Approval: 04/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOLVAPTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOLVAPTAN	JYNARQUE	36348		GPI-10 (3045406000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) (ICD-10 Q61.2, Q61.3) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient does NOT have end-stage renal disease (ESRD), including no renal transplantation or dialysis

   If yes, **approve for 6 months for all strengths as follows:**
   - **90mg-30mg (GPID or GPI-14): #2 per day.**
   - **45mg-15mg (GPID or GPI-14): #2 per day.**
   - **60mg-30mg (GPID or GPI-14): #2 per day.**
   - **30-15mg (GPID or GPI-14): #2 per day.**
   - **15-15mg (GPID or GPI-14): #2 per day.**
   - **15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #2 per day.**
   - **30mg (NDC 59148-0083-13) [FDB & Medi-Span]: #1 per day.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for approval:
   A. You have autosomal dominant polycystic kidney disease (ADPKD: a type of kidney condition)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
   D. You do NOT have end-stage renal disease (ESRD: advanced kidney disease), including no renal transplantation (kidney transplant) or dialysis (process of removing excess water, toxins from the blood)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOLVAPTAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) (ICD-10 Q61.2, Q61.3) **AND** meet the following criterion?
   - The patient has not progressed to end-stage renal disease (ESRD)

   If yes, **approve for 12 months for all strengths as follows:**
   - **90mg-30mg (GPID or GPI-14): #2 per day.**
   - **45mg-15mg (GPID or GPI-14): #2 per day.**
   - **60mg-30mg (GPID or GPI-14): #2 per day.**
   - **30-15mg (GPID or GPI-14): #2 per day.**
   - **15-15mg (GPID or GPI-14): #2 per day.**
   - **15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #2 per day.**
   - **30mg (NDC 59148-0083-13) [FDB & Medi-Span]: #1 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for renewal:
   A. You have autosomal dominant polycystic kidney disease (ADPKD: a type of kidney condition)
   B. You have NOT progressed to end stage renal disease (ESRD: advanced kidney disease)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jynarque.

REFERENCES

Jynarque [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; October 2020.

Created: 08/18
Effective: 07/01/25 Client Approval: 05/25 P&T Approval: 01/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOPIRAMATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOPIRAMATE	EPRONTIA, TOPIRAMATE		51457	GPI-14 (72600075002020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Groups G40.1, G40.2) or primary generalized tonic-clonic seizures (ICD-10 Group G40.3) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The requested medication will be used as initial monotherapy OR adjunctive therapy
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a contraindication to or is unable to swallow oral topiramate tablets or capsules
   - The patient had a trial of or contraindication to THREE preferred antiepileptic agents (e.g., carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide, topiramate tablets or capsules, lamotrigine)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day**.
   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome (ICD-10 Group G40.81) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The requested medication will be used as adjunctive therapy
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a contraindication to or is unable to swallow oral topiramate tablets or capsules
   - The patient had a trial of or contraindication to the standard of care agent: valproic acid or derivatives
   - The patient had a trial of or contraindication to TWO of the following preferred antiepileptic agents: Epidiolex, rufinamide, felbamate, clobazam, lamotrigine, clonazepam, generic topiramate tablets or capsules

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day.**
   If no, continue to #3.

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TOPIRAMATE

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of migraines (ICD-10 Group G43) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The requested medication will be used as preventative treatment of migraines
   - The patient is unable to take oral tablets or capsules
   - The patient had a trial of or contraindication to ONE preferred agent: Trokendi XR, generic topiramate tablet/sprinkle, topiramate ER sprinkle

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4mL per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOPIRAMATE (Eprontia)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Partial-onset seizures (a type of seizure)
      2. Primary generalized tonic-clonic seizures (a type of seizure)
      3. Seizures associated with Lennox-Gastaut syndrome (a type of seizure disorder in young children)
      4. Migraine (a type of headache)

   B. If you have partial-onset seizures or primary generalized tonic-clonic seizures, approval also requires:
      1. You are 2 years of age or older
      2. The requested medication will be used as initial monotherapy (one medication treatment) OR adjunctive therapy (medications taken together with)
      3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
      4. You have a contraindication to (harmful for you to use) or are unable to swallow oral topiramate tablets or capsules
      5. You have tried or have a contraindication to (harmful for you to use) THREE preferred anti-seizure medications (such as carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate tablets or capsules, lamotrigine)

   (Initial denial text continued on next page)

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TOPIRAMATE

INITIAL CRITERIA (CONTINUED)

C. If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:
1. You are 2 years of age or older
2. The requested medication will be used as adjunctive therapy (medications taken together with)
3. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
4. You have a contraindication to (harmful for you to use) or are unable to swallow oral topiramate tablets or capsules
5. You have tried or have a contraindication to (harmful for you to use) the standard of care medication: valproic acid or derivatives
6. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred anti-seizure medications: Epidiolex, rufinamide, felbamate, clobazam, lamotrigine, clonazepam, generic topiramate tablets or capsules

D. If you have migraines, approval also requires:
1. You are 12 years of age or older
2. The requested medication will be used as preventative treatment of migraines
3. You are unable to take oral tablets or capsules
4. You have tried or have a contraindication to (harmful for you to use) ONE preferred medication: Trokendi XR, generic topiramate tablet/sprinkle, topiramate extended release (ER) sprinkle

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TOPIRAMATE

RENEWAL CRITERIA

NOTE: For the diagnosis of migraines, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Groups G40.1, G40.2) or primary generalized tonic-clonic seizures (ICD-10 Group G40.3)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome (ICD-10 Group G40.81)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #16mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOPIRAMATE (Eprontia)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Partial-onset seizures (a type of seizure)
      2. Primary generalized tonic-clonic seizures (a type of seizure)
      3. Seizures associated with Lennox-Gastaut syndrome (a type of seizure disorder in young children)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eprontia.

REFERENCES

Eprontia [Prescribing Information]. Wilmington, MA: Azurity Pharmaceuticals, Inc.; March 2025.

Created: 02/22
Effective: 06/03/26 Client Approval: 06/26 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOREMIFENE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOREMIFENE CITRATE	FARESTON, TOREMIFENE CITRATE	11632		GPI-10 (2140268510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
- The patient is a postmenopausal female
- The patient has estrogen-receptor positive or unknown tumors

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOREMIFENE (Fareston)** requires the following rule(s) be met for approval:
A. You have metastatic breast cancer (cancer that has spread to other parts of the body)
B. You are a postmenopausal female (after menopause)
C. You have estrogen-receptor positive or unknown tumors

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Fareston.

REFERENCES
Fareston [Prescribing Information] Princeton, NJ: Kyowa Kirin, Inc.; December 2024.

Created: 08/13
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 08/13

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TORIPALIMAB-TPZI (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TORIPALIMAB-TPZI	LOQTORZI	49284		GPI-10 (2135797072)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or recurrent locally advanced nasopharyngeal carcinoma (NPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Loqtorzi will be used for first line treatment
   - Loqtorzi will be used in combination with cisplatin and gemcitabine

   If yes, **approve for 24 months by HICL or GPI-10 with a quantity limit of #6mL per 21 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of recurrent unresectable or metastatic nasopharyngeal carcinoma (NPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Loqtorzi will be used as a single agent
   - The patient experienced disease progression on or after a platinum-containing chemotherapy (e.g., cisplatin)

   If yes, **approve for lifetime by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TORIPALIMAB-TPZI (Loqtorzi)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Metastatic or recurrent locally advanced nasopharyngeal carcinoma (a type of neck cancer that has spread to other parts of the body or was previously treated and has spread to nearby tissue or lymph nodes)
      2. Recurrent unresectable or metastatic nasopharyngeal carcinoma (a type of neck cancer that was previously treated and unable to be removed by surgery or that has spread to other parts of the body)

   B. If you have metastatic or recurrent locally advanced nasopharyngeal carcinoma, approval also requires:
      1. You are 18 years of age or older
      2. Loqtorzi is for first-line treatment
      3. Loqtorzi will be used in combination with cisplatin and gemcitabine

   (Denial text continued on the next page)

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TORIPALIMAB-TPZI (NSA)

GUIDELINES FOR USE (CONTINUED)

C. If you have recurrent unresectable or metastatic nasopharyngeal carcinoma, approval also requires:

1. You are 18 years of age or older
2. Loqtorzi will be used as a single agent
3. You have experienced disease progression on or after a platinum-containing chemotherapy (such as cisplatin)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Loqtorzi.

REFERENCES

Loqtorzi [Prescribing Information]. Redwood City, CA: Coherus BioSciences, Inc.; October 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 01/01/24
Created: 12/23
Client Approval: 12/23
P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOVORAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOVORAFENIB	OJEMDA	49542		GPI-10 (2153207500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory low-grade glioma (LGG) (ICD-10 D33.2) **AND** meet the following criterion?
   - The patient's cancer has a BRAF fusion, BRAF rearrangement, or BRAF V600 mutation

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **100mg: #24 per 28 days.**
   - **25mg/mL: #96mL per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOVORAFENIB (Ojemda)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory low-grade glioma (LGG) (a type of brain cancer that has returned or did not respond to treatment)
   B. Your cancer has a BRAF fusion, BRAF rearrangement, or BRAF V600 mutation (types of abnormal changes in genes)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ojemda.

REFERENCES

Ojemda [Prescribing Information]. Brisbane, CA: Day One Biopharmaceuticals, Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/10/24
Created: 05/24
Client Approval: 05/24
P&T Approval: 07/24

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRABECTEDIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRABECTEDIN	YONDELIS	35367		GPI-10 (2110707500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic liposarcoma or leiomyosarcoma and meets the following criterion?
   - The patient has received prior therapy with an anthracycline-containing regimen such as doxorubicin

   If yes, **approve for 12 months by HICL or GPI-10.**

   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRABECTEDIN (Yondelis)** requires the following rule(s) be met for approval:
   A. You have unresectable or metastatic liposarcoma or leiomyosarcoma (cancer of the fat cells or muscles that cannot be removed with surgery or has spread to other parts of body).
   B. You have previously received therapy with an anthracycline-containing regimen such as doxorubicin.

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yondelis.

REFERENCES

Yondelis [Information]. Horsham, PA: Janssen Products; December 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 11/15
Client Approval: 04/20
P&T Approval: 11/15

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRALOKINUMAB-LDRM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRALOKINUMAB-LDRM	ADBRY	47741		GPI-10 (9027308045)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - Adbry will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Dupixent [dupilumab], Rinvoq [upadacitinib]) and is switching to Adbry
   - The patient has atopic dermatitis involving at least 10% of body surface area (BSA)
   - The patient has atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRALOKINUMAB-LDRM

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **ONE** of the following clinical standard of care therapies?
   - Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate)
   - Topical calcineurin inhibitor (e.g., Protopic [tacrolimus], Elidel [pimecrolimus])
   - Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
   - Topical AhR agonist (e.g., Vtama [tapinarof])
   - Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])
   - Phototherapy

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #6mL per 28 days.)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRALOKINUMAB-LDRM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for approval:

A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
D. You will NOT use Adbry concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)
E. You meet ONE of the following:
    1. You were previously stable on another biologic (such as Dupixent [dupilumab], Rinvoq [upadacitinib]) and are switching to Adbry
    2. You have atopic dermatitis (a type of skin condition) involving at least 10 percent of body surface area (BSA)
    3. You have atopic dermatitis (a type of skin condition) affecting the face, head, neck, hands, feet, groin, or intertriginous areas (areas between skin folds)
F. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care therapies:
    1. Topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate)
    2. Topical calcineurin inhibitor (such as Protopic [tacrolimus], Elidel [pimecrolimus])
    3. Topical PDE-4 (phosphodiesterase-4) inhibitor (such as Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
    4. Topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof])
    5. Topical JAK (Janus kinase) inhibitor (such as Opzelura [ruxolitinib])
    6. Phototherapy (a type of light therapy)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRALOKINUMAB-LDRM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on Adbry
   - Adbry will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4mL per 28 days.** If no, do not approve.

   RENEWAL DENIAL TEXT: Our guideline named **TRALOKINUMAB-LDRM (Adbry)** requires the following rule(s) be met for renewal:
   A. You have moderate to severe atopic dermatitis (AD: a type of skin condition)
   B. You have shown improvement while on Adbry
   C. You will NOT use Adbry concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adbry.

REFERENCES

Adbry [Prescribing Information]. Madison, NJ: LEO Pharma Inc.; June 2024.

Created: 01/22
Effective: 07/15/26 DMC Approval: 06/29/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMADOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAMADOL HCL	QDOLO, TRAMADOL HCL		48598	GPI-14 (65100095102005)	

GUIDELINES FOR USE

1. Is the request for the management of pain (ICD-10 R52) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's pain is severe enough to require an opioid analgesic
   - Alternative treatments for the patient's pain are inadequate
   - The patient had a trial of or contraindication to the preferred agent: generic tramadol IR tablet or a generic tramadol with acetaminophen product
   - The patient is unable to take oral solid formulations of tramadol or tramadol with acetaminophen (e.g., difficulty swallowing)

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #80mL per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRAMADOL (Qdolo)** requires the following rule(s) be met for approval:
   A. The request is for the management of pain
   B. You are 18 years of age or older
   C. Your pain is severe enough to require an opioid analgesic (type of pain medication)
   D. Alternative (other) treatments for your pain are inadequate (did not work)
   E. You have tried or have a contraindication to (harmful for you to use) the preferred medication: generic tramadol immediate-release (IR) tablet or a generic tramadol with acetaminophen product
   F. You are unable to take oral solid formulations (such as a tablet) of tramadol or tramadol with acetaminophen (such as with difficulty swallowing)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qdolo.

REFERENCES

Qdolo [Prescribing Information]. Athens, GA: Athena Bioscience, LLC; December 2025.

Created: 02/21
Effective: 03/04/26 Client Approval: 03/26 P&T Approval: 01/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST	40361		GPI-10 (2153357010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - Mekinist will be used as a single agent in a BRAF-inhibitor treatment-naive patient OR in combination with Tafinlar (dabrafenib)

   If yes, continue to #7.
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) (Group C34) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - Mekinist will be used in combination with Tafinlar (dabrafenib)

   If yes, continue to #7.
   If no, continue to #3.

3. Does the patient have a diagnosis of melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test
   - Mekinist will be used as an adjuvant therapy in combination with Tafinlar (dabrafenib)
   - There is involvement of lymph node(s), following complete resection

   If yes, continue to #7.
   If no, continue to #4.

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) (ICD-10 C73) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation
   - Mekinist will be used in combination with Tafinlar (dabrafenib)
   - The patient has no satisfactory locoregional treatment options available

   If yes, continue to #7.
   If no, continue to #5.

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of unresectable or metastatic solid tumor and meet **ALL** of the following criteria?
   - The patient is 1 year of age or older
   - The patient has a BRAF V600E mutation
   - Mekinist will be used in combination with Tafinlar (dabrafenib)
   - The patient's disease has progressed following prior treatment and has no satisfactory alternative treatment options

   If yes, continue to #7.
   If no, continue to #6.

6. Does the patient have a diagnosis of low-grade glioma (LGG) (ICD-10 D33.2) and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient has a BRAF V600E mutation
   - Mekinist will be used in combination with Tafinlar (dabrafenib)
   - The patient requires systemic therapy

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the request for the tablet formulation?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **2mg: #1 per day.**
   - **0.5mg: #3 per day.**

   If no, continue to #8.

8. Is the request for the oral solution **AND** the patient meets the following criterion?
   - The patient is unable to swallow Mekinist (trametinib) tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #42mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRAMETINIB (Mekinist)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed by surgery or has spread to other parts of the body)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   3. Melanoma (a type of skin cancer)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: a type of thyroid cancer that has spread to nearby tissue or lymph nodes or has spread to other parts of the body)
   5. Unresectable or metastatic solid tumor (tumor that cannot be removed by surgery or has spread to other parts of the body)
   6. Low-grade glioma (LGG: a type of brain cancer)

B. If you have unresectable or metastatic melanoma, approval also requires:
   1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. Mekinist will be used as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer) OR in combination with Tafinlar (dabrafenib)

C. If you have metastatic non-small cell lung cancer, approval also requires:
   1. You have a BRAF V600E mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. Mekinist will be used in combination with Tafinlar (dabrafenib)

D. If you have melanoma, approval also requires:
   1. You have a BRAF V600E or V600K mutation (abnormal change in gene) as detected by a Food and Drug Administration (FDA)-approved test
   2. Mekinist will be used as an adjuvant (add-on) therapy in combination with Tafinlar (dabrafenib)
   3. There is involvement of lymph node(s), following complete resection (surgical removal)

E. If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:
   1. You have a BRAF V600E mutation (abnormal change in gene)
   2. Mekinist will be used in combination with Tafinlar (dabrafenib)
   3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

(Denial text continued on next page)

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TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

F. If you have an unresectable or metastatic solid tumor, approval also requires:
1. You are 1 year of age or older
2. You have a BRAF V600E mutation (abnormal change in gene)
3. Mekinist will be used in combination with Tafinlar (dabrafenib)
4. Your disease has progressed following prior treatment and have no satisfactory alternative treatment options

G. If you have low-grade glioma, approval also requires:
1. You are 1 to 17 years of age
2. You have a BRAF V600E mutation (abnormal change in gene)
3. Mekinist will be used in combination with Tafinlar (dabrafenib)
4. You require systemic therapy (treatment that targets the entire body)

H. If the request is for the oral solution, approval also requires:
1. You are unable to swallow Mekinist (trametinib) tablets

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Mekinist.

REFERENCES
Mekinist [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 07/13
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB	HERCEPTIN	18801		GPI-10 (2117007000)	
TRASTUZUMAB-HYALURONIDASE-OYSK	HERCEPTIN HYLECTA	45653		GPI-10 (2199000272)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's cancer is HER2-overexpressing (HER2-positive), as detected by an FDA-approved companion diagnostic test for trastuzumab
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), Ogivri (trastuzumab-dkst)

   If yes, continue to #2.
   If no, continue to #4.

2. Will the requested medication be used as adjuvant therapy and the patient meets **ONE** of the following criteria?
   - The requested medication will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   - The requested medication will be used as part of a treatment regimen with docetaxel and carboplatin
   - The requested medication will be used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
   - **Herceptin: no quantity limit.**
   - **Herceptin Hylecta: #5mL per 21 days.**

   If no, continue to #3.

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE

GUIDELINES FOR USE (CONTINUED)

3. Is the patient's cancer metastatic and does the patient meet **ONE** of the following criteria?
   - The requested medication will be used in combination with paclitaxel
   - The requested medication will be used as a single agent in a patient who has received at least one chemotherapy regimen for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10 for all of the following:**
   - **Herceptin: no quantity limit.**
   - **Herceptin Hylecta: #5mL per 21 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The request is for Herceptin
   - The patient's cancer is HER2-overexpressing (HER2-positive), as detected by an FDA-approved companion diagnostic test for trastuzumab
   - Herceptin will be used in combination with cisplatin AND either Xeloda (capecitabine) or 5-fluorouracil
   - The patient has NOT received prior treatment for metastatic disease

   If yes, **approve Herceptin for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (Herceptin, Herceptin Hylecta)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Breast cancer
      2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

   (Denial text continued on next page)

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE

GUIDELINES FOR USE (CONTINUED)

B. If you have breast cancer, approval also requires:

1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for trastuzumab
2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), Ogivri (trastuzumab-dkst)
3. You meet ONE of the following:
   a. The requested medication will be used as adjuvant (additional) treatment, and you meet ONE of the following:
      i. The requested medication will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      ii. The requested medication will be used as part of a treatment plan with docetaxel and carboplatin
      iii. The requested medication will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)
   b. Your cancer is metastatic (has spread to other parts of the body), and you meet ONE of the following:
      i. The requested medication will be used in combination with paclitaxel
      ii. The requested medication will be used as a single medication if you have received at least one chemotherapy regimen (type of cancer treatment) for metastatic disease

C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. The request is for Herceptin
2. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for trastuzumab
3. Herceptin will be used in combination with cisplatin AND either Xeloda (capecitabine) or 5-fluorouracil
4. You have NOT received prior treatment for metastatic disease

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Herceptin or Herceptin Hylecta.

REFERENCES

Herceptin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2024.
Herceptin Hylecta [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2024.

Created: 08/12
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 04/20

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-ANNS (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-ANNS	KANJINTI	45796		GPI-10 (2117007014)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer and meet **ALL** of the following criteria?
   - The request is for adjuvant therapy
   - The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
   - The patient meets **ONE** of the following:
     - The requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
     - The requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
     - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
   - The patient meets **ONE** of the following:
     - The requested medication is being used in combination with paclitaxel for first-line treatment
     - The requested medication is being used as a single agent in a patient who has previously received **ONE** or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
   - The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB-ANNS (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRASTUZUMAB-ANNS (Kanjinti)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Breast cancer
   2. Metastatic breast cancer (breast cancer that has spread to other parts of body)
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. The request is for adjuvant (add-on) therapy
   3. You meet **ONE** of the following:
      a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

C. If you have metastatic breast cancer, approval also requires:
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. You meet **ONE** of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously received **ONE** or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

D. If you have metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body), approval also requires:
   1. You have HER2-positive tumor (you have a type of protein present in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

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TRASTUZUMAB-ANNS (NSA)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kanjinti.

REFERENCES

Kanjinti [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; July 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 07/19
Client Approval: 03/21
P&T Approval: 07/19

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STANDARD NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-DKST (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-DKST	OGIVRI	44673		GPI-10 (2117007030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer and meet **ALL** of the following criteria?
   - The request is for adjuvant therapy
   - The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
   - The patient meets **ONE** of the following:
     - The requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
     - The requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
     - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
   - The patient meets **ONE** of the following:
     - The requested medication is being used in combination with paclitaxel for first-line treatment
     - The requested medication is being used as a single agent in patients who have previously received **ONE** or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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TRASTUZUMAB-DKST (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
   - Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRASTUZUMAB-DKST (Ogivri)** requires the following rule(s) be met for approval:
   A. You have **ONE** of the following diagnoses:
      1. Breast cancer
      2. Metastatic breast cancer (cancer has spread to other parts of the body)
      3. Metastatic gastric or gastroesophageal junction adenocarcinoma (type of cancer in the stomach and/or lower throat that has spread to other parts of the body)

   B. If you have breast cancer, approval also requires:
      1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
      2. The request is for adjuvant (add-on) therapy
      3. You meet **ONE** of the following:
         a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
         c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

   (Denial text continued on next page)

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TRASTUZUMAB-DKST (NSA)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic breast cancer, approval also requires:

1. You have HER2-positive metastatic breast cancer (you have a type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
2. You meet **ONE** of the following:
   a. The requested medication is being used in combination with paclitaxel for first-line treatment
   b. The requested medication is being used as a single agent if you have previously received **ONE** or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

D. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. You have HER2-positive metastatic cancer (you have a type of protein and the cancer has spread to other parts of the body) as detected by a Food and Drug Administration-(FDA)-approved test
2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ogivri.

REFERENCES

Ogivri [Prescribing Information]. Steinhausen, Switzerland: Mylan GmbH; April 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 11/19
Client Approval: 03/21
P&T Approval: 01/18

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-DTTB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-DTTB	ONTRUZANT	45571		GPI-10 (2117007034)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer and meet **ALL** of the following criteria?
   - The request is for adjuvant therapy
   - The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
   - The patient meets **ONE** of the following:
     - The requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
     - The requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
     - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Kanjinti, Trazimera, or Ogivri

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
   - The patient meets **ONE** of the following:
     - The requested medication is being used in combination with paclitaxel for first-line treatment
     - The requested medication is being used as a single agent in a patient who has previously received ONE or more chemotherapy regimens for metastatic disease
   - The patient had a trial of or contraindication to **ONE** of the following preferred agents: Kanjinti, Trazimera, or Ogivri

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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TRASTUZUMAB-DTTB (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
   - The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRASTUZUMAB- DTTB (Ontruzant)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Breast cancer
      2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
      3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

   B. If you have breast cancer, approval also requires:
      1. The request is for adjuvant (add-on) therapy
      2. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
      3. You meet ONE of the following:
         a. The requested medication is being used as part of a treatment plan that contains doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
         c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin
      4. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

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TRASTUZUMAB-DTTB (NSA)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic breast cancer, approval also requires:
1. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
2. You meet ONE of the following:
   a. The requested medication is being used in combination with paclitaxel for first-line treatment
   b. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)
3. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

D. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You have HER2-positive tumor (type of protein present in stomach cancer) as detected by a Food and Drug Administration-approved test
2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ontruzant.

REFERENCES

Ontruzant [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; March 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 04/20
Client Approval: 03/21
P&T Approval: 04/20

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-PKRB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-PKRB	HERZUMA	45541		GPI-10 (2117007060)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
   - The request is for adjuvant therapy
   - The patient meets **ONE** of the following:
     - The requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
     - The requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
     - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)
   - The patient had a trial of or contraindication to **ONE** of the following preferred agents: Kanjinti, Trazimera, or Ogivri

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
   - The patient meets **ONE** of the following:
     - The requested medication is being used in combination with paclitaxel for first-line treatment
     - The requested medication is being used as a single agent in patients who have previously received ONE or more chemotherapy regimens for metastatic disease
   - The patient had a trial of or contraindication to **ONE** of the following preferred agents: Kanjinti, Trazimera, or Ogivri

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

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TRASTUZUMAB-PKRB (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
   - The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRASTUZUMAB-PKRB (Herzuma)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Breast cancer
      2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
      3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or lower throat that has spread to other parts of the body)

   B. If you have breast cancer, approval also requires:
      1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
      2. The request is for adjuvant (add-on) treatment
      3. You meet ONE of the following:
         a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
         b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
         c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin
      4. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

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TRASTUZUMAB-PKRB (NSA)

GUIDELINES FOR USE (CONTINUED)

C. If you have metastatic breast cancer, approval also requires:

1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
2. You meet ONE of the following:
   a. The requested medication is being used in combination with paclitaxel for first-line treatment
   b. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)
3. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

D. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. You have HER2-positive tumor (type of protein found in stomach cancer) as detected by a Food and Drug Administration (FDA)-approved test
2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Herzuma.

REFERENCES

Herzuma [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals; May 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 03/20
Client Approval: 03/21
P&T Approval: 04/20

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-QYYP (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-QYYP	TRAZIMERA	45657		GPI-10 (2117007065)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer and meet **ALL** of the following criteria?
   - The request is for adjuvant therapy
   - The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
   - The patient meets **ONE** of the following:
     - The requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
     - The requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
     - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
   - The patient meets **ONE** of the following:
     - The requested medication is being used in combination with paclitaxel for first-line treatment
     - The requested medication is being used as a single agent in a patient who has previously received ONE or more chemotherapy regimens for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
   - The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
   - The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   - The patient has not received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

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TRASTUZUMAB-QYYP (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRASTUZUMAB- QYYP (Trazimera)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Breast cancer
   2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:
   1. The request is for adjuvant (add-on) therapy
   2. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
   3. You meet ONE of the following:
      a. The requested medication is being used as part of a treatment plan that contains doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
      b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
      c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

C. If you have metastatic breast cancer, approval also requires:
   1. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
   2. You meet ONE of the following:
      a. The requested medication is being used in combination with paclitaxel for first-line treatment
      b. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

D. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
   1. You have HER2-positive tumor (type of protein present in stomach cancer) as detected by a Food and Drug Administration-approved test
   2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
   3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

(Denial text continued on next page)

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TRASTUZUMAB-QYYP (NSA)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trazimera.

REFERENCES

Trazimera [Prescribing Information]. New York, NY: Pfizer Ireland Pharmaceuticals; March 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 02/20
Client Approval: 03/21
P&T Approval: 04/19

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-STRF

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRASTUZUMAB-STRF	HERCESSI	49554		GPI-10 (2117007040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's cancer is HER2-overexpressing (HER2-positive), as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), Ogivri (trastuzumab-dkst)

   If yes, continue to #2.
   If no, continue to #4.

2. Will Hercessi be used as adjuvant therapy and the patient meets **ONE** of the following criteria?
   - Hercessi will be used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
   - Hercessi will be used as part of a treatment regimen with docetaxel and carboplatin
   - Hercessi will be used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, Idamycin [idarubicin], Ellence [epirubicin], Valstar [valrubicin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. Is the patient's cancer metastatic and does the patient meet **ONE** of the following criteria?
   - Hercessi will be used in combination with paclitaxel
   - Hercessi will be used as a single agent in a patient who has received at least one chemotherapy regimen for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB-STRF

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient's cancer is HER2-overexpressing (HER2-positive), as detected by an FDA-approved companion diagnostic test for a trastuzumab product
   - Hercessi will be used in combination with cisplatin AND either Xeloda (capecitabine) or 5-fluorouracil
   - The patient has NOT received prior treatment for metastatic disease

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRASTUZUMAB-STRF (Hercessi)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Breast cancer
      2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

   B. If you have breast cancer, approval also requires:
      1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
      2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Kanjinti (trastuzumab-anns), Trazimera (trastuzumab-qyyp), Ogivri (trastuzumab-dkst)
      3. You meet ONE of the following:
         a. Hercessi will be used as adjuvant (additional) treatment, and you meet ONE of the following:
            i. Hercessi will be used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
            ii. Hercessi will be used as part of a treatment plan with docetaxel and carboplatin
            iii. Hercessi will be used as a single medication following multi-modality anthracycline based therapy (therapy using a class of cancer medications that combines more than one method of treatment), such as daunorubicin, doxorubicin, Idamycin (idarubicin), Ellence (epirubicin), Valstar (valrubicin)

   (Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

b. Your cancer is metastatic (has spread to other parts of the body), and you meet ONE of the following:
   i. Hercessi will be used in combination with paclitaxel
   ii. Hercessi will be used as a single medication if you have received at least one chemotherapy regimen (type of cancer treatment) for metastatic disease

C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

1. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive, as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test for a trastuzumab product
2. Hercessi will be used in combination with cisplatin AND either Xeloda (capecitabine) or 5-fluorouracil
3. You have NOT received prior treatment for metastatic disease

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hercessi and Herceptin.

REFERENCES

Hercessi [Prescribing Information]. Raleigh, NC: Accord BioPharma Inc.; September 2024.
Herceptin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2024.

Created: 12/24
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRAZODONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRAZODONE HCL	RALDESY	01652		GPI-10 (5812008010)	BRAND = RALDESY

GUIDELINES FOR USE

1. Does the patient have a diagnosis of major depressive disorder (MDD) (ICD-10 Groups F32, F33) **AND** meet the following criterion?
   - The patient has a contraindication to OR is unable to swallow trazodone tablets

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #40mL per day.** If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRAZODONE (Raldesy)** requires the following rule(s) be met for approval:
   A. You have major depressive disorder (a type of mental illness)
   B. You have a contraindication to (harmful for you to use) OR are unable to swallow trazodone tablets

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Raldesy.

REFERENCES

Raldesy [Prescribing Information]. Parsippany, NJ: Validus Pharmaceuticals LLC; February 2025.

Created: 03/25
Effective: 04/01/25 Client Approval: 03/25 P&T Approval: 04/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREMELIMUMAB-ACTL (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREMELIMUMAB-ACTL	IMJUDO	48415		GPI-10 (2135528010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (uHCC) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- Imjudo will be used in combination with Imfinzi (durvalumab)
- The patient has not received previous treatment with Imjudo per lifetime

If yes, **approve for 30 days by HICL or GPI-10 with a quantity limit of #15 mL and a fill count of 1.**

If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
- The patient does not have sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
- Imjudo will be used in combination with Imfinzi (durvalumab) and platinum-based chemotherapy (e.g., cisplatin, carboplatin)
- The patient has not received a total of 5 doses of Imjudo per lifetime

If yes, **approve for 5 months by HICL or GPI-10 with a quantity limit of #3.75 mL per fill and a total fill count of 5 fills.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREMELIMUMAB-ACTL (Imjudo)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable hepatocellular carcinoma (uHCC: a type of liver cancer that cannot be removed by surgery)
   2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)

(Denial text continued on the next page)

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TREMELIMUMAB-ACTL (NSA)

GUIDELINES FOR USE (CONTINUED)

B. If you have unresectable hepatocellular carcinoma, approval also requires:
1. You are 18 years of age or older
2. Imjudo will be used in combination with Imfinzi (durvalumab)
3. You have not received previous treatment with Imjudo in your lifetime

C. If you have metastatic non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
2. You do not have sensitizing epidermal growth factor receptor (EGFR: a type of protein) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (a type of abnormal gene)
3. Imjudo will be used in combination with Imfinzi (durvalumab) and platinum-based chemotherapy (a type of cancer treatment, such as cisplatin, carboplatin)
4. You have not received a total of 5 doses of Imjudo in your lifetime

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imjudo.

REFERENCES

Imjudo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/01/24
Created: 01/23
Client Approval: 03/24
P&T Approval: 01/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL-ORENITRAM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL DIOLAMINE	ORENITRAM ER	40827		GPI-10 (4017008005)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient does NOT have severe hepatic impairment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL-ORENITRAM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL-ORENITRAM** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
C. You do NOT have severe hepatic (liver) impairment
D. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL-ORENITRAM

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL-ORENITRAM** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Orenitram.

REFERENCES

Orenitram [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; August 2023.

Created: 09/05
Effective: 07/01/25 Client Approval: 06/25 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL-REMODULIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL SODIUM	REMODULIN, TREPROSTINIL		17433 17436 17434 17435 58175	GPI-14 (40170080002080, 40170080002070, 40170080002050, 40170080002060, 40170080002040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for continuation of Remodulin (treprostinil) therapy from a hospital discharge?

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, continue to #4.

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TREPROSTINIL-REMODULIN

INITIAL CRITERIA (CONTINUED)

4. Is the request for a new start of Remodulin (treprostinil) therapy and the patient meets **ONE** of the following criteria?
   - The patient is intermediate or high risk
   - The patient had a trial of or contraindication to TWO of the following clinical standard of care agents from different drug classes:
     - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
     - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
     - Oral cGMP stimulator (e.g., Adempas [riociguat])

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL-REMODULIN** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   B. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   C. Your pulmonary arterial hypertension (PAH: a type of heart and lung condition) is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      1. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
      2. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
      3. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

   (Initial denial text continued on next page)

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TREPROSTINIL-REMODULIN

INITIAL CRITERIA (CONTINUED)

D. For new start requests of Remodulin (treprostinil), approval also requires ONE of the following:
1. You are intermediate or high risk
2. You have tried or have a contraindication to (harmful for you to use) TWO of the following clinical standard of care medications from different medication classes:
   a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
   c. Oral cGMP stimulator (such as Adempas [riociguat])

E. If you are continuing current Remodulin (treprostinil) therapy from a hospital discharge, there is no additional requirement for approval.

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL-REMODULIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2)?

   If yes, **approve all strengths for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL-REMODULIN** requires the following rule(s) be met for renewal:
   A. You have pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Remodulin.

REFERENCES

Remodulin [Prescribing Information]. Research Triangle Park, NC; United Therapeutics Corp.; October 2023.

Created: 03/23
Effective: 05/20/26 Client Approval: 05/26 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL-TYVASO DPI

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL	TYVASO DPI	36541		GPI-10 (4017008000)	FDB & Medi-Span: BRAND = TYVASO DPI%

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) **AND** meet the following criterion?
    - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

    If yes, continue to #2.
    If no, continue to #3.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
    - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
    - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
    - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

    If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 fill per 28 days for all of the following (NOTE: Enter a Min Day Supply of 28 days):**
    - **16-32mcg Titration Kit**
    - **16-32-48mcg Titration Kit**
    - **48-80mcg Titration Kit**
    - **16mcg**
    - **32mcg**
    - **48mcg**
    - **64mcg**
    - **80mcg**
    - **32-48mcg**
    - **32-64mcg**
    - **48-64mcg**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL-TYVASO DPI

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23) **AND** meet the following criterion?
    - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

    If yes, continue to #4.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient's PH-ILD diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
    - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
    - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
    - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

    If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 fill per 28 days for all of the following (NOTE: Enter a Min Day Supply of 28 days):**
    - **16-32mcg Titration Kit**
    - **16-32-48mcg Titration Kit**
    - **48-80mcg Titration Kit**
    - **16mcg**
    - **32mcg**
    - **48mcg**
    - **64mcg**
    - **80mcg**
    - **32-48mcg**
    - **32-64mcg**
    - **48-64mcg**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL-TYVASO DPI

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL-TYVASO DPI** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

B. If you have pulmonary arterial hypertension (WHO Group 1), approval also requires:
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension (PAH: a type of heart and lung condition) diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary arterial hypertension [a type of heart and lung condition]) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary arterial hypertension [a type of heart and lung condition]) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary arterial hypertension [a type of heart and lung condition]) greater than 2 Wood units

C. If you have pulmonary hypertension associated with interstitial lung disease (WHO Group 3), approval also requires:
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension [a type of heart and lung condition]) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension [a type of heart and lung condition]) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension [a type of heart and lung condition]) greater than 2 Wood units

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TREPROSTINIL-TYVASO DPI

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)
   - Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #1 fill per 28 days for all of the following (NOTE: Enter a Min Day Supply of 28 days):**
   - **16mcg**
   - **32mcg**
   - **48mcg**
   - **64mcg**
   - **80mcg**
   - **32-48mcg**
   - **32-64mcg**
   - **48-64mcg**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL-TYVASO DPI** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
      2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyvaso DPI.

REFERENCES

Tyvaso DPI [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; October 2024.

Created: 03/24
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL-TYVASO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL	TYVASO		27489 27491 27492	GPI-14 (40170080002020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for a total of 12 months by GPID or GPI-14. Please enter TWO authorizations as follows:**
   - **FIRST APPROVAL: Approve Tyvaso Starter Kit for 1 month for 1 fill (PAC NOTE: Enter a Min Day Supply of 28 days).**
   - **SECOND APPROVAL: Approve Tyvaso or Tyvaso Refill Kit for 11 months (enter a start date of 3 days BEFORE the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL-TYVASO

INITIAL CRITERIA (CONTINUED)

4. Is the patient's PH-ILD diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve for a total of 12 months by GPID or GPI-14. Please enter TWO authorizations as follows:**
   - **FIRST APPROVAL: Approve Tyvaso Starter Kit for 1 month for 1 fill (PAC NOTE: Enter a Min Day Supply of 28 days).**
   - **SECOND APPROVAL: Approve Tyvaso or Tyvaso Refill Kit for 11 months (enter a start date of 3 days BEFORE the end date of the first approval).**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL-TYVASO

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL-TYVASO** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

B. If you have pulmonary arterial hypertension (WHO Group 1), approval also requires:
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

C. If you have pulmonary hypertension associated with interstitial lung disease (WHO Group 3), approval also requires:
   1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
   2. Your pulmonary hypertension diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
      a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TREPROSTINIL-TYVASO

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)
   - Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23)

   If yes, **approve Tyvaso or Tyvaso Refill Kit for 12 months by GPID or GPI-14.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL-TYVASO** requires the following rule(s) be met for renewal:
   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
      2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyvaso.

REFERENCES

Tyvaso [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp.; May 2022.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL-YUTREPIA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL SODIUM	YUTREPIA		57781 57782 57783 57784	GPI-10 (4017008010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD- 10 I27.0, Group I27.2) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's PAH diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve all strengths for 12 months by GPID or GPI-10 with a quantity limit of #1 fill per 28 days as follows (PAC NOTE: Enter a Min Day Supply of 28 days):**
   - **26.5 mcg**
   - **53 mcg**
   - **79.5 mcg**
   - **106 mcg**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL-YUTREPIA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the patient's PH-ILD diagnosis confirmed by right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) of greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) of greater than 2 Wood units (WU)

   If yes, **approve all strengths for 12 months by GPID or GPI-10 with a quantity limit of #1 fill per 28 days as follows (PAC NOTE: Enter a Min Day Supply of 28 days):**
   - **26.5 mcg**
   - **53 mcg**
   - **79.5 mcg**
   - **106 mcg**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL-YUTREPIA** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
      2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

   (Initial denial text continued on next page)

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TREPROSTINIL-YUTREPIA

INITIAL CRITERIA (CONTINUED)

B. If you have pulmonary arterial hypertension (WHO Group 1), approval also requires:
1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
2. Your pulmonary arterial hypertension is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
   c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

C. If you have pulmonary hypertension associated with interstitial lung disease (WHO Group 3), approval also requires:
1. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor) or pulmonologist (lung/breathing doctor)
2. Your pulmonary hypertension diagnosis is confirmed by ALL of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   a. Mean pulmonary artery pressure (PAP: a type of measurement for pulmonary hypertension) greater than 20 mmHg
   b. Pulmonary capillary wedge pressure (PCWP: a type of measurement for pulmonary hypertension) less than or equal to 15 mmHg
   c. Pulmonary vascular resistance (PVR: a type of measurement for pulmonary hypertension) greater than 2 Wood units

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TREPROSTINIL-YUTREPIA

RENEWAL CRITERIA

1. Does the patient have **ONE** of the following diagnoses?
   - Pulmonary arterial hypertension (PAH) (WHO Group 1) (ICD-10 I27.0, Group I27.2)
   - Pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) (ICD-10 I27.23)

   If yes, **approve the requested strength for 12 months by GPID or GPI-10 with a quantity limit of #1 fill per 28 days as follows (PAC NOTE: Enter a Min Day Supply of 28 days):**
   - **26.5 mcg**
   - **53 mcg**
   - **79.5 mcg**
   - **106 mcg**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TREPROSTINIL-YUTREPIA** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Pulmonary arterial hypertension (PAH: a type of heart and lung condition) (World Health Organization [WHO] Group 1: a way to classify the severity of disease)
      2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) (World Health Organization [WHO] Group 3: a way to classify the severity of disease)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yutrepia.

REFERENCES

Yutrepia [Prescribing Information]. Morrisville, NC: Liquidia Technologies, Inc.; May 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE CAPSULE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIENTINE HCL	SYPRINE, CLOVIQUE, TRIENTINE HCL	01109		GPI-10 (9920002010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - The requested medication will be used with a dietary plan to maintain a copper intake of less than 0.9 mg/day
   - The patient had a trial of or contraindication to the preferred agent: penicillamine (Depen, Cuprimine)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have genetic testing confirming an ATP7B mutation?

   If yes, **approve for lifetime by GPID or GPI-14 for all strengths with a quantity limit as follows:**
   - **250 mg: #8 per day.**
   - **500 mg: #4 per day.**

   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has a 24-hour urinary copper excretion (greater than 40 micrograms/24 hours)
   - The patient has a liver biopsy with copper dry weight greater than 75 micrograms/gram
   - The patient has a serum ceruloplasmin level of less than 20 mg/dL

   If yes, **approve for lifetime by GPID or GPI-14 for all strengths with a quantity limit as follows:**
   - **250 mg: #8 per day.**
   - **500 mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRIENTINE CAPSULE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRIENTINE CAPSULE (Syprine, Clovique)** requires the following rule(s) be met for approval:

A. You have Wilson's disease (a type of genetic disorder)
B. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
C. The requested medication will be used with a dietary plan to maintain a copper intake of less than 0.9 mg/day
D. You have tried or have a contraindication to (harmful for you to use) the preferred medication: penicillamine (Depen, Cuprimine)
E. You meet ONE of the following:
    1. You have genetic testing confirming an ATP7B mutation (an abnormal change in a type of gene)
    2. You meet ONE of the following:
        a. You have a 24-hour urinary copper excretion (a type of lab test) (greater than 40 micrograms/24 hours)
        b. You have a liver biopsy (removal of cells or tissue from the liver for examination) with copper dry weight greater than 75 micrograms/gram
        c. You have a serum ceruloplasmin (a type of lab test) level less than 20mg/dL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Syprine, Clovique, or trientine hydrochloride.

REFERENCES

Syprine [Prescribing Information]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.
Clovique [Prescribing Information]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; September 2019.
Trientine hydrochloride capsules [Prescribing Information]. East Brunswick, NJ: Rising Pharma Holdings, Inc.; August 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIENTINE TABLET

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIENTINE TETRAHYDROCHLORIDE	CUVRIOR	45888		GPI-10 (9920002020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Wilson's disease (ICD-10 E83.01) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a hepatologist or gastroenterologist
   - Cuvrior will be used with a dietary plan to maintain a copper intake of less than 0.9 mg/day
   - The patient had a trial of the clinical standard of care agent: penicillamine (Depen, Cuprimine) for at least one year prior to starting Cuvrior
   - The patient had a trial of the preferred agent: trientine hydrochloride (Syprine)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have genetic testing confirming an ATP7B mutation?

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, continue to #3.

3. Does the patient meet **ONE** of the following criteria?
   - The patient has a 24-hour urinary copper excretion (greater than 40 micrograms/24 hours)
   - The patient has a liver biopsy with copper dry weight greater than 75 micrograms/gram
   - The patient has a serum ceruloplasmin level of less than 20 mg/dL

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #10 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRIENTINE TABLET

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRIENTINE TABLET (Cuvrior)** requires the following rule(s) be met for approval:

A. You have Wilson's disease (a type of genetic disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a hepatologist (a type of liver doctor) or gastroenterologist (a type of digestive system doctor)
D. Cuvrior will be used with a dietary plan to maintain a copper intake of less than 0.9 mg/day
E. You have tried the clinical standard of care medication: penicillamine (Depen, Cuprimine) for at least one year prior to starting Cuvrior
F. You have tried the preferred medication: trientine hydrochloride (Syprine)
G. You meet ONE of the following:
    1. You have genetic testing confirming an ATP7B mutation (an abnormal change in a type of gene)
    2. You meet ONE of the following:
        a. You have a 24-hour urinary copper excretion (a type of lab test) (greater than 40 micrograms/24 hours)
        b. You have a liver biopsy (removal of cells or tissue from the liver for examination) with copper dry weight greater than 75 micrograms/gram
        c. You have a serum ceruloplasmin (a type of lab test) level less than 20mg/dL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cuvrior.

REFERENCES

Cuvrior [Prescribing Information]. Chicago, IL: Orphalan SA; April 2022.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIFLURIDINE/TIPIRACIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIFLURIDINE/ TIPIRACIL HCL	LONSURF	42544		GPI-10 (2199000275)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy [e.g., Zaltrap (ziv-aflibercept), Cyramza (ramucirumab)]
   - Lonsurf will be used as a single agent OR in combination with bevacizumab

   If yes, continue to #2.
   If no, continue to #4.

2. Is the patient's metastatic colorectal cancer RAS wild-type?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **15/6.14mg: #100 per 28 days.**
   - **20/8.19mg: #80 per 28 days.**

3. Has the patient had previous treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **15/6.14mg: #100 per 28 days.**
   - **20/8.19mg: #80 per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRIFLURIDINE/TIPIRACIL

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma (ICD-10 C16.0; Group C15) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **15/6.14mg: #100 per 28 days.**
   - **20/8.19mg: #80 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Metastatic colorectal cancer (a type of digestive system cancer that has spread to other parts of the body)
      2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)

   B. If you have metastatic colorectal cancer, approval also requires:
      1. You are 18 years of age or older
      2. Lonsurf will be used as a single agent OR in combination with bevacizumab
      3. You had previous treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) in combination with an anti-VEGF biological therapy such as Zaltrap (ziv-aflibercept) or Cyramza (ramucirumab)
      4. If your metastatic colorectal cancer is RAS wild-type (a type of gene), you also had a previous treatment with an anti-EGFR agent such as Erbitux (cetuximab), Vectibix (panitumumab)

   C. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
      1. You are 18 years of age or older
      2. You had previous treatment with at least two prior lines of chemotherapy (drugs used to treat cancer) that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2 (type of gene)/neu-targeted therapy

   (Denial text continued on next page)

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TRIFLURIDINE/TIPIRACIL

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lonsurf.

REFERENCES

Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; August 2023.

Library	Commercial	NSA
Yes	Yes	No

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Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIHEPTANOIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIHEPTANOIN	DOJOLVI	46676		GPI-10 (8020008000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) (ICD-10 Group E71.31)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient's diagnosis confirmed by **TWO** of the following?
   - Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
   - Low enzyme activity in cultured fibroblasts
   - One or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?
   - The patient is symptomatic (e.g., rhabdomyolysis, cardiomyopathy) for LC-FAOD
   - Therapy is prescribed by or in consultation with a gastroenterologist or physician specialist in medical genetics/inherited metabolic disorders
   - The patient had a trial of or contraindication to the clinical standard of care agent: commercial MCT oil (medical food product)

   If yes, **approve for 4 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRIHEPTANOIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for approval:

A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
B. Your diagnosis is confirmed by TWO of the following:
    1. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
    2. Low enzyme activity in cultured fibroblasts (a type of cell found in the body)
    3. One or more known pathogenic mutations (abnormal changes) in *CPT2, ACADVL, HADHA, or HADHB* (types of genes)
C. You are symptomatic for LC-FAOD (for example you have rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [a type of heart condition])
D. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions) or physician specialist in medical genetics/inherited metabolic disorders
E. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: commercial MCT oil (a medical food product)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIHEPTANOIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) (ICD-10 Group E71.31) **AND** meet the following criterion?
   - The patient has experienced a positive clinical response (e.g., improved exercise tolerance) or stabilization of clinical status compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for renewal:
   A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
   B. You have experienced a positive clinical response (such as improved exercise tolerance) or stabilization of clinical status compared to baseline

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dojolvi.

REFERENCES

Dojolvi [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc.; June 2025.

Created: 10/20
Effective: 05/13/26 Client Approval: 05/26 P&T Approval: 10/20

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRILACICLIB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRILACICLIB DIHYDROCHLORIDE	COSELA	47121		GPI-10 (2175657020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) and meet **ALL** of the following?
   - The patient is 18 years of age or older
   - Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression
   - Cosela will be administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 fill per 21 days.** If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRILACICLIB (Cosela)** requires the following rule(s) be met for approval:
   A. You have extensive-stage small cell lung cancer
   B. You are 18 years of age or older
   C. Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression (decreased bone marrow activity causing fewer red blood cells, white blood cells, and platelets)
   D. Cosela will be given prior to a platinum/etoposide-containing regimen or topotecan-containing regimen

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cosela.

REFERENCES

Cosela [Prescribing Information]. Durham, NC: G1 Therapeutics, Inc.; February 2021.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/21
Created: 05/21
Client Approval: 05/21
P&T Approval: 04/21

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIPTORELIN-TRELSTAR (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIPTORELIN PAMOATE	TRELSTAR	23164		GPI-10 (2140505020)	BRAND ≠ TRIPTODUR

GUIDELINES FOR USE

1. Is the requested medication for gender dysphoria (ICD-10 Group F64) as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

   If yes, **approve for 12 months by HICL or GPI-10 (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**

   If no, continue to #2.

2. Does the patient who have a diagnosis of advanced prostate cancer (ICD-10 C61)?

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **3.75 mg: #1 per 4 weeks.**
   - **11.25 mg: #1 per 12 weeks.**
   - **22.5 mg: #1 per 24 weeks.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIPTORELIN-TRELSTAR** requires the following rule(s) be met for approval:

   A. You have ONE of the following diagnoses:
      1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
      2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)

   B. If you have gender dysphoria, approval also requires:
      1. Only medications supported by the compendia (accepted medical references such as DrugDex strength of recommendation Class I, IIa, or IIb) for treatment of gender dysphoria (your gender identity conflicts with your sex assigned at birth) may be approved

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trelstar.

REFERENCES

Trelstar [Prescribing Information]. Wayne, PA: Verity Pharmaceuticals Inc.; October 2020.

Created: 03/18
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 04/26

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIPTORELIN-TRIPTODUR (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIPTORELIN PAMOATE	TRIPTODUR		43603	GPI-10 (3008007040)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria?

   If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**
   If no, continue to #2.

2. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 8 years of age at the onset of CPP
   - There is documentation of pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #1 per 24 weeks.**
   If no, continue to #4.

3. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a pediatric endocrinologist
   - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
   - The patient is younger than 9 years of age at the onset of CPP
   - There is documentation of pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #1 per 24 weeks.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TRIPTORELIN-TRIPTODUR (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRIPTORELIN-TRIPTODUR** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
   2. Central precocious puberty (CPP: early sexual development in girls and boys)

B. If you are female and have central precocious puberty, approval also requires:
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 8 years of age when your condition started
   5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

C. If you are male and have central precocious puberty, approval also requires:
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (a type of hormone doctor)
   3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
   4. You are/were younger than 9 years of age when your condition started
   5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TRIPTORELIN-TRIPTODUR (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnosis of gender dysphoria, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of central precocious puberty (CPP) and meet **ALL** of the following criteria?
   - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
   - The patient has not reached the actual age which corresponds to their current pubertal age

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #1 per 24 weeks.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TRIPTORELIN-TRIPTODUR** requires the following rule(s) be met for renewal:
   A. You have central precocious puberty (CPP: early sexual development in girls and boys)
   B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   C. You have not reached the actual age which corresponds to your current pubertal age

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Triptodur.

REFERENCES

Triptodur [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; April 2022.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 01/23/23
Created: 03/18
Client Approval: 01/23
P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TROFINETIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TROFINETIDE	DAYBUE, DAYBUE STIX	48773		GPI-10 (7465307500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Rett syndrome (ICD-10 F84.2) **AND** meet the following criterion?
   - The patient is 2 years of age or older

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   200mg/mL: #120mL per day.
   - **5000mg: #4 per day.**
   - **6000mg: #4 per day.**
   - **8000mg: #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TROFINETIDE (Daybue, Daybue Stix)** requires the following rule(s) be met for approval:
   A. You have Rett syndrome (a type of nervous system disorder)
   B. You are 2 years of age or older

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daybue and Daybue Stix.

REFERENCES

Daybue [Prescribing Information]. San Diego, CA: Acadia Pharmaceuticals Inc.; December 2025.
Daybue Stix [Prescribing Information]. San Diego, CA: Acadia Pharmaceuticals Inc.; December 2025.

Created: 04/23
Effective: 01/26/26 Client Approval: 01/26 P&T Approval: 04/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TUCATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TUCATINIB	TUKYSA	46459		GPI-10 (2117008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced unresectable or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's breast cancer is human epidermal growth factor receptor 2 (HER2)-positive
   - The patient has received at least one anti-HER2-based regimens (i.e., trastuzumab or trastuzumab with pertuzumab) in the metastatic setting
   - Tukysa will be used in combination with trastuzumab and capecitabine

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **50mg: #10 per day.**
   - **150mg: #4 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of unresectable or metastatic colorectal cancer (ICD-10 C19) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's colorectal cancer is RAS wild-type, human epidermal growth factor receptor 2 (HER2)-positive
   - The patient's cancer has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
   - Tukysa will be used in combination with trastuzumab

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **50mg: #10 per day.**
   - **150mg: #4 per day.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TUCATINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TUCATINIB (Tukysa)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Advanced unresectable or metastatic breast cancer (cancer that cannot be removed with surgery or has spread to other parts of the body)
   2. Unresectable or metastatic colorectal cancer (a type of digestive cancer that cannot be removed with surgery or has spread to other parts of the body)

B. If you have advanced unresectable or metastatic breast cancer, approval also requires:
   1. Your breast cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   2. You have received at least one anti-HER2-based treatment (trastuzumab or trastuzumab with pertuzumab) for metastatic (has spread to other parts of the body) disease
   3. Tukysa will be used in combination with trastuzumab and capecitabine

C. If you have unresectable or metastatic colorectal cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your colorectal cancer is RAS wild-type (a type of gene), human epidermal growth factor receptor 2 (HER2: a type of protein)-positive
   3. Your cancer has progressed (worsened) following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (medications used to treat cancer)
   4. Tukysa will be used in combination with trastuzumab

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tukysa.

REFERENCES

Tukysa [Prescribing Information]. Bothell, WA: Seagen, Inc.; January 2023.

Created: 08/20
Effective: 05/05/25 Client Approval: 04/25 P&T Approval: 04/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UBLITUXIMAB-XIIY

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UBLITUXIMAB-XIIY	BRIUMVI	48560		GPI-10 (6240508505)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (ICD-10 G35), to include clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the preferred agent: Kesimpta (ofatumumab)

   If yes, **approve for a total of 12 months by HICL or GPI-10 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL: Approve for 1 month with a quantity limit of #24 mL (four 150 mg/6 mL vials) per 28 days.**
   - **SECOND APPROVAL: Approve for 11 months with a quantity limit of #18 mL (three 150 mg/6 mL vials) per 24 weeks. (Please enter a start date of 5 months AFTER the START date of the first approval.)**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #18 mL (three 150 mg/6 mL vials) per 24 weeks.**

   If no, do not approve.

   DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UBLITUXIMAB-XIIY (Briumvi)** requires the following rules be met for approval:
   A. You have a relapsing form of multiple sclerosis (MS: a type of nerve disorder), which includes clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms or disease returns and goes away) or active secondary progressive disease (advanced disease)
   B. You are 18 years of age or older
   C. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Kesimpta (ofatumumab)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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UBLITUXIMAB-XIIY

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Briumvi.

REFERENCES

Briumvi [Prescribing Information]. Morrisville, NC: TG Therapeutics, Inc; August 2025.

Created: 01/23
Effective: 01/01/26 Client Approval: 02/23 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UBROGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UBROGEPANT	UBRELVY	46273		GPI-10 (6770108000)	

GUIDELINES FOR USE

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Ubrelvy will NOT be used concurrently with other cGRP inhibitors (e.g., Zavzpret [zavegepant]) for the acute treatment of migraines
   - The patient had a trial of or contraindication to the clinical standard of care agent: ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **UBROGEPANT (Ubrelvy)** requires the following rule(s) be met for approval:
   A. The request is for the acute (quick onset) treatment of migraines (a type of headache)
   B. You are 18 years of age or older
   C. You will NOT use Ubrelvy concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Zavzpret [zavegepant]) for the acute (quick onset) treatment of migraines (a type of headache)
   D. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ubrelvy.

REFERENCES

Ubrelvy [Prescribing Information]. North Chicago, IL: AbbVie Inc.; June 2025.

Created: 01/20
Effective: 04/01/26 Client Approval: 03/26 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

UPADACITINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
UPADACITINIB	RINVOQ	45955		GPI-10 (6660307200)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of RA
   - The patient had a trial of or contraindication to 3 months of treatment with ONE clinical standard of care agent: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA
   - The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Enbrel [etanercept])

   If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **1mg/mL: #12mL per day.**

   If no, continue to #3.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Opzelura (ruxolitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, continue to #4.
   If no, continue to #6.

4. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and is switching to Rinvoq
   - The patient has atopic dermatitis involving at least 10 percent of body surface area (BSA)
   - The patient has atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See initial denial text at the end of the guideline.

5. Has the patient had a trial of or contraindication to **ONE** of the following clinical standard of care therapies?
   - Topical corticosteroid (e.g., hydrocortisone, clobetasol propionate, halobetasol propionate)
   - Topical calcineurin inhibitor (e.g., Elidel [pimecrolimus], Protopic [tacrolimus])
   - Topical PDE-4 inhibitor (e.g., Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast])
   - Topical AhR agonist (e.g., Vtama [tapinarof])
   - Topical JAK inhibitor (e.g., Opzelura [ruxolitinib])
   - Phototherapy

   IF YES, APPROVE FOR 6 MONTHS BY HICL OR GPI-10 WITH A QUANTITY LIMIT OF #1 PER DAY.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., adalimumab-ryvk/adalimumab-aaty), OR has received at least one approved systemic therapy (e.g., Skyrizi [risankizumab-rzaa]) if TNF blockers are clinically inadvisable

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CD
   - The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., adalimumab-ryvk/adalimumab-aaty), OR has received at least one approved systemic therapy (e.g., Skyrizi [risankizumab-rzaa]) if TNF blockers are clinically inadvisable

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #8.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of AS
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)
   - The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #9.

9. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of nr-axSpA
   - The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., Cimzia [certolizumab])
   - The patient had a trial of or contraindication to the clinical standard of care agent: an NSAID (e.g., ibuprofen, naproxen, meloxicam)

   If yes, continue to #10.
   If no, continue to #11.

10. Does the patient meet **ONE** of the following criteria?
    - The patient was previously stable on another biologic and is switching to Rinvoq
    - The patient has C-reactive protein (CRP) levels above the upper limit of normal
    - The patient has sacroiliitis on magnetic resonance imaging (MRI)

    If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
    - The patient is 2 years of age or older
    - Therapy is prescribed by or in consultation with a rheumatologist
    - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of pJIA
    - The patient had an inadequate response or intolerance to at least ONE tumor necrosis factor (TNF) blocker (e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

    If yes, **approve for 6 months by GPID or GPI-14 for all strengths as follows:**
    - **15mg: #1 per day.**
    - **1mg/mL: #12mL per day.**

    If no, continue to #12.

12. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - The patient has completed, started, or will soon start a tapering course of glucocorticoids (e.g., prednisone)
    - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Actemra [tocilizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

    If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 per day.**
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Ankylosing spondylitis (AS: a type of joint condition)
   7. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   8. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   9. Giant cell arteritis (GCA: a type of inflammatory condition)

B. If you have moderate to severe rheumatoid arthritis, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)
   4. You have tried at least 3 months of or have a contraindication to (harmful for you to use) ONE clinical standard of care medication: a conventional synthetic DMARD (disease-modifying anti-rheumatic drug), such as methotrexate dose of at least 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Enbrel [etanercept])

D. If you have moderate to severe atopic dermatitis, approval also requires:
1. You are 12 years of age or older
2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Opzelura (ruxolitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)
4. You meet ONE of the following:
   a. You were previously stable on another biologic (such as Adbry [tralokinumab-ldrm], Dupixent [dupilumab]) and are switching to Rinvoq
   b. You have atopic dermatitis (a type of skin condition) involving at least 10 percent of body surface area (BSA)
   c. You have atopic dermatitis (a type of skin condition) affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)
5. You have tried or have a contraindication to (harmful for you to use) ONE of the following clinical standard of care therapies: topical corticosteroid (such as hydrocortisone, clobetasol propionate, halobetasol propionate), topical calcineurin inhibitor (such as Elidel [pimecrolimus], Protopic [tacrolimus]), topical phosphodiesterase-4 (PDE-4) inhibitor (such as Eucrisa [crisaborole], Adquey [difamilast], Zoryve [roflumilast]), topical aryl hydrocarbon receptor (AhR) agonist (such as Vtama [tapinarof]), topical Janus kinase (JAK) inhibitor (such as Opzelura [ruxolitinib]), phototherapy (light therapy)

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty), OR you have received at least one approved systemic therapy (treatment that targets the entire body such as Skyrizi [risankizumab-rzaa]) if TNF blockers are clinically inadvisable (not recommended)

F. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty), OR you have received at least one approved systemic therapy (treatment that targets the entire body such as Skyrizi [risankizumab-rzaa]) if TNF blockers are clinically inadvisable (not recommended)

G. If you have ankylosing spondylitis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (nonsteroidal anti-inflammatory drug such as ibuprofen, naproxen, meloxicam)
5. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

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UPADACITINIB

INITIAL CRITERIA (CONTINUED)

H. If you have non-radiographic axial spondyloarthritis, approval also requires:
1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)
4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as Cimzia [certolizumab])
5. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: an NSAID (non-steroidal anti-inflammatory drug, such as ibuprofen, naproxen, meloxicam)
6. You meet ONE of the following:
   a. You were previously stable on another biologic and are switching to Rinvoq
   b. You have C-reactive protein (CRP: a measure of how much inflammation is in the body) levels above the upper limit of normal
   c. You have sacroiliitis (a type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI: a type of imaging lab)

I. If you have polyarticular juvenile idiopathic arthritis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)
4. You had an inadequate response (medication did not work) or intolerance (side effect) to at least ONE tumor necrosis factor (TNF) blocker (such as adalimumab-ryvk/adalimumab-aaty, Enbrel [etanercept])

J. If you have giant cell arteritis, approval also requires:
1. You are 18 years of age or older
2. You have completed, started, or will soon start a tapering course (slowly lowering the dose to stop use) of glucocorticoids (such as prednisone)
3. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)

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UPADACITINIB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) (ICD-10 M05.9, M06.9; Groups M05.7, M05.8, M06.0, M06.8) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of RA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **1mg/mL: #12mL per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe atopic dermatitis (AD) (ICD-10 Group L20) and meet **ALL** of the following criteria?
   - The patient has shown improvement while on therapy
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Dupixent [dupilumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Opzelura (ruxolitinib)], PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]) for the treatment of AD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #4.

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #6.

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) (ICD-10 Group M45 except Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of AS

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #7.

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA) (ICD-10 Group M45.A) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Taltz [ixekizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of nr-axSpA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #8.

8. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (ICD-10 M08.3, Group M08.0) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Xeljanz (tofacitinib)], PDE-4 inhibitor) for the treatment of pJIA

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**
   - **15mg: #1 per day.**
   - **1mg/mL: #12mL per day.**

   If no, continue to #9.

9. Does the patient have a diagnosis of giant cell arteritis (GCA) (ICD-10 M31.6, M31.5) **AND** meet the following criterion?
   - Rinvoq will NOT be used concurrently with another systemic biologic (e.g., Actemra [tocilizumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor) for the treatment of GCA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: Our guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe atopic dermatitis (AD: a type of skin condition)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)
   5. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   6. Ankylosing spondylitis (AS: a type of joint condition)
   7. Non-radiographic axial spondyloarthritis (nr-axSpA: a type of joint condition)
   8. Polyarticular juvenile idiopathic arthritis (pJIA: a type of joint condition)
   9. Giant cell arteritis (GCA: a type of inflammatory condition)

B. If you have moderate to severe rheumatoid arthritis, renewal also requires:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of rheumatoid arthritis (a type of joint condition)

C. If you have psoriatic arthritis, renewal also requires:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. If you have moderate to severe atopic dermatitis, renewal also requires:
   1. You have shown improvement while on therapy
   2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Dupixent [dupilumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Opzelura (ruxolitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Eucrisa (crisaborole)]) for the treatment of atopic dermatitis (a type of skin condition)

(Renewal denial text continued on next page)

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UPADACITINIB

RENEWAL CRITERIA (CONTINUED)

E. If you have moderate to severe ulcerative colitis, renewal also requires:
1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

F. If you have moderate to severe Crohn's disease, renewal also requires:
1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

G. If you have ankylosing spondylitis, renewal also requires:
1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) score while on therapy
2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ankylosing spondylitis (a type of joint condition)

H. If you have non-radiographic axial spondyloarthritis, renewal also requires:
1. You have experienced or maintained an improvement of at least 50 percent or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: a type of disease evaluation tool) score while on therapy
2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Taltz [ixekizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of non-radiographic axial spondyloarthritis (a type of joint condition)

I. If you have polyarticular juvenile idiopathic arthritis, renewal also requires:
1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Xeljanz (tofacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of polyarticular juvenile idiopathic arthritis (a type of joint condition)

J. If you have giant cell arteritis, renewal also requires:
1. You will NOT use Rinvoq concurrently (at the same time) with another systemic biologic (such as Actemra [tocilizumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of giant cell arteritis (a type of inflammatory condition)

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UPADACITINIB

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Rinvoq.

REFERENCES
Rinvoq [Prescribing Information]. North Chicago, IL: AbbVie Inc.; October 2025.

Created: 08/19
Effective: 07/15/26 DMC Approval: 06/29/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URIDINE TRIACETATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
URIDINE TRIACETATE	XURIDEN		39481	GPI-10 (3090387520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary orotic aciduria (HOA) (ICD-10 E79.89) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a prescriber specializing in inherited metabolic diseases

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at end of the guideline.

2. Is the patient's HOA diagnosis confirmed by **ALL** of the following criteria?
   - The patient has a genetic mutation in the uridine monophosphate synthase (UMPS) gene
   - The patient has an elevated urine orotic acid level according to an age-specific reference range

   If yes, **approve for 6 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) be met for approval:
   A. You have hereditary orotic aciduria (HOA a type of rare genetic disorder)
   B. Therapy is prescribed by or in consultation with a doctor specializing in inherited metabolic diseases (genetic diseases that result in metabolism problems)
   C. Your HOA diagnosis is confirmed by ALL of the following:
      1. You have a genetic mutation (abnormal change in gene) in the uridine monophosphate synthase (UMPS) gene
      2. You have elevated urine orotic acid levels (high levels of a type of substance in the rune) according to your age-specific reference range

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URIDINE TRIACETATE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary orotic aciduria (HOA) (ICD-10 E79.89) **AND** meet the following criterion?
   - The patient has had improvement from baseline or stabilization of age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) while on treatment with Xuriden

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) to be met for renewal:
   A. You have hereditary orotic aciduria (HOA: a type of rare genetic disorder)
   B. You have had improvement from baseline (before treatment) or stabilization of age dependent hematologic parameters (blood lab tests such as neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) while on treatment with Xuriden

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xuriden.

REFERENCES

Xuriden [Prescribing Information]. Gaithersburg, MD: Wellstat Therapeutics Corporation. December 2019.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/16
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 05/16

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB	STELARA	36187		GPI-10 (9025058500, 5250407000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a dermatologist
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, face, genital area, or scalp
   - Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #6.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

3. Is the patient 6 to 11 years of age and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
     - **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Yesintek, ustekinumab-aekn, and Steqeyma)**

     If no, continue to #4.

4. Is the patient 12 to 17 years of age and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Icotyde (icotrokinra)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
     - **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Yesintek, ustekinumab-aekn, and Steqeyma)**

     If no, continue to #5.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

5. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - o Tremfya (guselkumab)
     - o Skyrizi (risankizumab-rzaa)
     - o Enbrel (etanercept)
     - o Otezla (apremilast)
     - o Taltz (ixekizumab)
     - o Sotyktu (deucravacitinib)
     - o Bimzelx (bimekizumab-bkzx)
     - 0 Adalimumab-ryvk/adalimumab-aaty
     - 0 Icotyde (icotrokinra)

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
     - **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Yesintek, ustekinumab-aekn, and Steqeyma)**

     If no, do not approve.
     DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
- Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
- Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

If yes, continue to #7.
If no, continue to #9.

7. Is the patient 6 to 17 years of age and meet **ALL** of the following criteria?
- The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
- The patient had a trial of or contraindication to TWO of the following preferred agents:
  - Enbrel (etanercept)
  - Otezla (apremilast)
  - Tremfya (guselkumab)
  - Skyrizi (risankizumab-rzaa)
  - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])
  - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])

[**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
- **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Yesintek, ustekinumab-aekn, and Steqeyma)**

If no, continue to #8.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

8. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Otezla (apremilast)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Sotyktu (deucravacitinib)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
   - **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Yesintek, ustekinumab-aekn, and Steqeyma)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #10.
   If no, continue to #13.

10. Is the patient 2 to 5 years of age **AND** meet the following criterion?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
    - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
    - **(NOTE: Enter a proactive PA for Yesintek, ustekinumab-aekn, and Steqeyma for 6 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
      - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

    If no, continue to #11.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

11. Is the patient 6 to 17 years of age and meet **ALL** of the following criteria?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
    - The patient had a trial of or contraindication to the following preferred agent: adalimumab-ryvk/adalimumab-aaty

    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
    - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
    - **(NOTE: Enter a proactive PA for Yesintek, ustekinumab-aekn, and Steqeyma for 6 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
        - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

    If no, continue to #12.

12. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
    - The patient had a trial of or contraindication to TWO of the following preferred agents:
        - Skyrizi (risankizumab-rzaa)
        - Tremfya (guselkumab)
        - Omvoh (mirikizumab-mrkz)
        - Adalimumab-ryvk/adalimumab-aaty
        - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
    - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
    - **(NOTE: Enter a proactive PA for Yesintek, ustekinumab-aekn, and Steqeyma for 6 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
        - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

13. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
    - Therapy is prescribed by or in consultation with a gastroenterologist
    - Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

    If yes, continue to #14.
    If no, do not approve.
    DENIAL TEXT: See the initial denial text at the end of the guideline.

14. Is the patient 2 to 4 years of age **AND** meets the following criterion?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
    - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
    - **(NOTE: Enter a proactive PA for Yesintek, ustekinumab-aekn, and Steqeyma for 6 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
      - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

    If no, continue to #15.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

15. Is the patient 5 to 17 years of age and meets **ALL** of the following criteria?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
    - The patient had a trial of or contraindication to the following preferred agent: adalimumab-ryvk/adalimumab-aaty
      [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

      If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
      - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
      - **(NOTE: Enter a proactive PA for Yesintek, ustekinumab-aekn, and Steqeyma for 6 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
        - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

      If no, continue to #16.

16. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
    - The patient had a trial of or contraindication to TWO of the following preferred agents:
      - Skyrizi (risankizumab-rzaa)
      - Tremfya (guselkumab)
      - Omvoh (mirikizumab-mrkz)
      - Adalimumab-ryvk/adalimumab-aaty
      - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
      - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
        [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

      If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
      - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
      - **(NOTE: Enter a proactive PA for Yesintek, ustekinumab-aekn, and Steqeyma for 6 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
        - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

      If no, do not approve.
      DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: Our guideline named **USTEKINUMAB (Stelara)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe plaque psoriasis, approval also requires:
   1. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   2. You have psoriasis (a type of skin condition) covering 3 percent or more of body surface area (BSA) OR you have psoriatic lesions (rashes) affecting the hands, feet, face, genital area, or scalp
   3. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You are 6 to 11 years of age and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Tremfya (guselkumab), Skyrizi (risankizumab- rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab)
   b. You are 12 to 17 years of age and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Tremfya (guselkumab), Skyrizi (risankizumab- rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Icotyde (icotrokinra)
   c. You are 18 years of age or older and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you use) TWO of the following preferred medications:
         1. Tremfya (guselkumab)
         2. Skyrizi (risankizumab-rzaa)
         3. Enbrel (etanercept)
         4. Otezla (apremilast)
         5. Taltz (ixekizumab)
         6. Sotyktu (deucravacitinib)
         7. Bimzelx (bimekizumab-bkzx)
         8. Adalimumab-ryvk/adalimumab-aaty
         9. Icotyde (icotrokinra)

C. If you have psoriatic arthritis, approval also requires:

1. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

3. You meet ONE of the following:
   a. You are 6 to 17 years of age and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab- aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         1. Enbrel (etanercept)
         2. Otezla (apremilast)
         3. Tremfya (guselkumab)
         4. Skyrizi (risankizumab-rzaa)
         5. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
         6. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
   b. You are 18 years of age or older and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab- aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         1. Enbrel (etanercept)
         2. Otezla (apremilast)
         3. Tremfya (guselkumab)
         4. Skyrizi (risankizumab-rzaa)
         5. Taltz (ixekizumab)
         6. Bimzelx (bimekizumab-bkzx)
         7. Sotyktu (deucravacitinib)
         8. Adalimumab-ryvk/adalimumab-aaty
         9. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
         10. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

D. If you have moderate to severe Crohn's disease, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
3. You meet ONE of the following:
   a. You are 2 to 5 years of age AND meet the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   b. You are 6 to 17 years of age AND meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: adalimumab-ryvk/adalimumab-aaty
   c. You are 18 years of age or older and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         1. Skyrizi (risankizumab-rzaa)
         2. Tremfya (guselkumab)
         3. Omvoh (mirikizumab-mrkz)
         4. Adalimumab-ryvk/adalimumab-aaty
         5. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab- aaty])

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

E. If you have moderate to severe ulcerative colitis, approval also requires:

1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
3. You meet ONE of the following:
   a. You are 2 to 4 years of age AND meet the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab- aekn, Steqeyma (ustekinumab-stba)
   b. You are 5 to 17 years of age AND meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab- aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: adalimumab-ryvk/adalimumab-aaty
   c. You are 18 years of age or older and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab- aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         1. Skyrizi (risankizumab-rzaa)
         2. Tremfya (guselkumab)
         3. Omvoh (mirikizumab-mrkz)
         4. Adalimumab-ryvk/adalimumab-aaty
         5. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         6. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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USTEKINUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   - Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #5.

2. Is the patient 6 to 11 years of age and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #3.

3. Is the patient 12 to 17 years of age and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Tremfya (guselkumab), Skyrizi (risankizumab-rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Icotyde (icotrokinra)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #4.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

4. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - o Tremfya (guselkumab)
     - o Skyrizi (risankizumab-rzaa)
     - o Enbrel (etanercept)
     - o Otezla (apremilast)
     - o Taltz (ixekizumab)
     - o Sotyktu (deucravacitinib)
     - o Bimzelx (bimekizumab-bkzx)
     - 0 Adalimumab-ryvk/adalimumab-aaty
     - 0 Icotyde (icotrokinra)

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

     If yes, continue to #6.
     If no, continue to #8.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

6. Is the patient 6 to 17 years of age and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Otezla (apremilast)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Xeljanz IR (tofacitinib IR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #7.

7. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Enbrel (etanercept)
     - Otezla (apremilast)
     - Tremfya (guselkumab)
     - Skyrizi (risankizumab-rzaa)
     - Taltz (ixekizumab)
     - Bimzelx (bimekizumab-bkzx)
     - Sotyktu (deucravacitinib)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])
     - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty, Enbrel])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, continue to #9.
   If no, continue to #12.

9. Is the patient 2 to 5 years of age **AND** meet the following criterion?
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days**.
   If no, continue to #10.

10. Is the patient 6 to 17 years of age and meet **ALL** of the following criteria?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
    - The patient had a trial of or contraindication to the following preferred agent: adalimumab-ryvk/adalimumab-aaty
      [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days**.
    If no, continue to #11.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

11. Is the patient 18 years of age or older and meet **ALL** of the following criteria?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
    - The patient had a trial of or contraindication to TWO of the following preferred agents:
      - Skyrizi (risankizumab-rzaa)
      - Tremfya (guselkumab)
      - Omvoh (mirikizumab-mrkz)
      - Adalimumab-ryvk/adalimumab-aaty
      - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

12. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
    - Stelara will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

    If yes, continue to #13.
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

13. Is the patient 2 to 4 years of age **AND** meets the following criterion?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)

    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
    If no, continue to #14.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

14. Is the patient 5 to 17 years of age and meets **ALL** of the following criteria?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
    - The patient had a trial of or contraindication to the following preferred agent: adalimumab-ryvk/adalimumab-aaty

    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
    If no, continue to #15.

15. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
    - The patient had a trial of or contraindication to ONE of the following preferred agents: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
    - The patient had a trial of or contraindication to TWO of the following preferred agents:
        - Skyrizi (risankizumab-rzaa)
        - Tremfya (guselkumab)
        - Omvoh (mirikizumab-mrkz)
        - Adalimumab-ryvk/adalimumab-aaty
        - Xeljanz (tofacitinib IR or XR) (**NOTE**: Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
        - Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

    [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
    If no, do not approve.
    DENIAL TEXT: See the renewal denial text at the end of the guideline.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: Our guideline named **USTEKINUMAB (Stelara)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe plaque psoriasis, renewal also requires:
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   3. You meet ONE of the following:
      a. You are 6 to 11 years of age and meet ALL of the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
         ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Tremfya (guselkumab), Skyrizi (risankizumab- rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab)
      b. You are 12 to 17 years of age and meet ALL of the following:
         i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
         ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Tremfya (guselkumab), Skyrizi (risankizumab- rzaa), Enbrel (etanercept), Otezla (apremilast), Taltz (ixekizumab), Icotyde (icotrokinra)

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

c. You are 18 years of age or older and meet ALL of the following:
   i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   ii. You have tried or have a contraindication to (harmful for you use) TWO of the following preferred medications:
      1. Tremfya (guselkumab)
      2. Skyrizi (risankizumab-rzaa)
      3. Enbrel (etanercept)
      4. Otezla (apremilast)
      5. Taltz (ixekizumab)
      6. Sotyktu (deucravacitinib)
      7. Bimzelx (bimekizumab-bkzx)
      8. Adalimumab-ryvk/adalimumab-aaty
      9. Icotyde (icotrokinra)

C. If you have psoriatic arthritis, renewal also requires:

1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
2. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)
3. You meet ONE of the following:
   a. You are 6 to 17 years of age and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         1. Enbrel (etanercept)
         2. Otezla (apremilast)
         3. Tremfya (guselkumab)
         4. Skyrizi (risankizumab-rzaa)
         5. Xeljanz IR (tofacitinib immediate-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])
         6. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as Enbrel])

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

b. You are 18 years of age or older and meet ALL of the following:
   i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      1. Enbrel (etanercept)
      2. Otezla (apremilast)
      3. Tremfya (guselkumab)
      4. Skyrizi (risankizumab-rzaa)
      5. Taltz (ixekizumab)
      6. Bimzelx (bimekizumab-bkzx)
      7. Sotyktu (deucravacitinib)
      8. Adalimumab-ryvk/adalimumab-aaty
      9. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty, Enbrel])
      10. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab- aaty, Enbrel])

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

D. If you have moderate to severe Crohn's disease, renewal also requires:

1. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
2. You meet ONE of the following:
   a. You are 2 to 5 years of age AND meet the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   b. You are 6 to 17 years of age AND meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: adalimumab-ryvk/adalimumab-aaty
   c. You are 18 years of age or older and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         1. Skyrizi (risankizumab-rzaa)
         2. Tremfya (guselkumab)
         3. Omvoh (mirikizumab-mrkz)
         4. Adalimumab-ryvk/adalimumab-aaty
         5. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab- aaty])

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

E. If you have moderate to severe ulcerative colitis, renewal also requires:

1. You will NOT use Stelara concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
2. You meet ONE of the following:
   a. You are 2 to 4 years of age AND meet the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
   b. You are 5 to 17 years of age AND meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab-aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) the following preferred medication: adalimumab-ryvk/adalimumab-aaty
   c. You are 18 years of age or older and meet ALL of the following:
      i. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Yesintek (ustekinumab-kfce), ustekinumab- aekn, Steqeyma (ustekinumab-stba)
      ii. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
         1. Skyrizi (risankizumab-rzaa)
         2. Tremfya (guselkumab)
         3. Omvoh (mirikizumab-mrkz)
         4. Adalimumab-ryvk/adalimumab-aaty
         5. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE**: Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
         6. Rinvoq (upadacitinib) (**NOTE**: Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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USTEKINUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Stelara.

REFERENCES

Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2026.

Created: 10/09
Effective: 09/09/26 Client Approval: 09/26 DMC Approval: 09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB-AEKN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB-AEKN	USTEKINUMAB-AEKN, SELARSDI	49526		GPI-10 (9025058502, 5250407002)	GCN ≠ 57717

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB-AEKN

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to the requested medication
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
   - **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Yesintek and Steqeyma)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
   - **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Yesintek and Steqeyma)**

   If no, continue to #5.

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USTEKINUMAB-AEKN

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
   - **(NOTE: Enter a proactive PA for Yesintek and Steqeyma for 6 months by HICL or GPI- 10 with a quantity limit of #1 per 56 days.**
     - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
   - **(NOTE: Enter a proactive PA for Yesintek and Steqeyma for 6 months by HICL or GPI- 10 with a quantity limit of #1 per 56 days.**
     - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB-AEKN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB-AEKN (Selarsdi)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe plaque psoriasis, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to the requested medication
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

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USTEKINUMAB-AEKN

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-AEKN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - The requested medication will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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USTEKINUMAB-AEKN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB-AEKN (Selarsdi)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe plaque psoriasis, renewal also requires:
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

C. If you have psoriatic arthritis, renewal also requires:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. If you have moderate to severe Crohn's disease, renewal also requires:
   1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. If you have moderate to severe ulcerative colitis, renewal also requires:
   1. You will NOT use the requested medication concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase- 4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-AEKN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ustekinumab-aekn and Stelara.

REFERENCES

Ustekinumab-aekn [Prescribing Information]. Parsippany, NJ: Teva Pharmaceuticals; October 2024.
Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2026.

Created: 02/25
Effective: 09/09/26 Client Approval: 09/26 DMC Approval: 09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB-KFCE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB-KFCE	YESINTEK	50041		GPI-10 (5250407079, 9025058578)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB-KFCE

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Yesintek
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
   - **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Ustekinumab-aekn and Steqeyma)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
   - **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Ustekinumab-aekn and Steqeyma)**

   If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
   - **(NOTE: Enter a proactive PA for ustekinumab-aekn and Steqeyma for 6 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
     - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
   - **(NOTE: Enter a proactive PA for ustekinumab-aekn and Steqeyma for 6 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
     - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB-KFCE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB-KFCE (Yesintek)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe plaque psoriasis, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of drug that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Yesintek
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

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USTEKINUMAB-KFCE

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-KFCE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Yesintek will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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USTEKINUMAB-KFCE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB-KFCE (Yesintek)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe plaque psoriasis, renewal also requires:
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

C. If you have psoriatic arthritis, renewal also requires:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. If you have moderate to severe Crohn's disease, renewal also requires:
   1. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. If you have moderate to severe ulcerative colitis, renewal also requires:
   1. You will NOT use Yesintek concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-KFCE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yesintek and Stelara.

REFERENCES

Yesintek [Prescribing Information]. Cambridge, MA: Biocon Biologics Inc.; January 2026.
Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2026.

Created: 02/25
Effective: 09/09/26 Client Approval: 09/26 DMC Approval: 09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

USTEKINUMAB-STBA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
USTEKINUMAB-STBA	STEQEYMA	50109		GPI-10 (9025058577, 5250407078)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a dermatologist
   - Steqeyma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) OR PUVA (phototherapy) for the treatment of PsO
   - The patient has a contraindication or intolerance to both clinical standard of care therapies: an immunosuppressant AND PUVA (phototherapy) for the treatment of PsO
   - The patient is switching from a different biologic (e.g., Humira [adalimumab]), PDE-4 inhibitor (e.g., Otezla [apremilast]), or JAK inhibitor for the same indication

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic and is switching to Steqeyma
   - The patient has psoriasis covering 3 percent or more of body surface area (BSA)
   - The patient has psoriatic lesions affecting the hands, feet, face, genital area, or scalp

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
   - **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Yesintek and ustekinumab-aekn)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist or dermatologist
   - Steqeyma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days. (Please enter a 1 month approval by HICL or GPI-10 with a quantity limit of #1mL per 28 days.)**
   - **(NOTE: Enter a proactive PA for 6 months by HICL or GPI-10 as stated above for ALL of the following: Yesintek and ustekinumab-aekn)**

   If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Steqeyma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
   - **(NOTE: Enter a proactive PA for Yesintek and ustekinumab-aekn for 6 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
     - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

   If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Steqeyma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.**
   - **(NOTE: Enter a proactive PA for Yesintek and ustekinumab-aekn for 6 months by HICL or GPI-10 with a quantity limit of #1 per 56 days.**
     - **Enter a one fill approval for 130mg/26mL for 1 month by GPID or GPI-14 with a quantity limit of #104mL per 56 days.)**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB-STBA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB-STBA (Steqeyma)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe plaque psoriasis, approval also requires:
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor)
   3. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)
   4. You meet ONE of the following:
      a. You have had at least a 3-month trial of ONE clinical standard of care therapy: an oral immunosuppressant (cyclosporine, methotrexate, tacrolimus) or PUVA (phototherapy: a type of light therapy) for the treatment of plaque psoriasis (a type of skin condition)
      b. You have a contraindication (harmful for you to use) or intolerance (side effect) to both clinical standard of care therapies: an immunosuppressant (a type of medication that decreases the body's immune response) and PUVA (phototherapy) for the treatment of plaque psoriasis (a type of skin condition)
      c. You are switching from a different biologic (such as Humira [adalimumab]), PDE-4 (phosphodiesterase-4) inhibitor (such as Otezla [apremilast]), or JAK (Janus kinase) inhibitor for the same indication
   5. You meet ONE of the following:
      a. You were previously stable on another biologic and are switching to Steqeyma
      b. You have psoriasis covering 3 percent or more of body surface area (BSA)
      c. You have psoriatic lesions (rashes) affecting your hands, feet, face, genital area, or scalp

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USTEKINUMAB-STBA

INITIAL CRITERIA (CONTINUED)

C. If you have psoriatic arthritis, approval also requires:
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or dermatologist (a type of skin doctor)
3. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis a type of skin and joint condition)

D. If you have moderate to severe Crohn's disease, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. If you have moderate to severe ulcerative colitis, approval also requires:
1. You are 2 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-STBA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) (ICD-10 L40.0) and meet **ALL** of the following criteria?
   - The patient has achieved or maintained clear or minimal disease OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50 percent or more
   - Steqeyma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor, PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsO

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) (ICD-10 Group L40.5) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   - Steqeyma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor [e.g., Otezla (apremilast)]) for the treatment of PsA

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 84 days.**
   If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) **AND** meet the following criterion?
   - Steqeyma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) **AND** meet the following criterion?
   - Steqeyma will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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USTEKINUMAB-STBA

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **USTEKINUMAB-STBA (Steqeyma)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe plaque psoriasis (PsO: a type of skin condition)
   2. Psoriatic arthritis (PsA: a type of skin and joint condition)
   3. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   4. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe plaque psoriasis, renewal also requires:
   1. You have achieved or maintained clear or minimal disease OR a decrease in Psoriasis Area and Severity Index (PASI: used to measure the severity and extent of psoriasis) of at least 50 percent or more
   2. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor, PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of plaque psoriasis (a type of skin condition)

C. If you have psoriatic arthritis, renewal also requires:
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor [such as Otezla (apremilast)]) for the treatment of psoriatic arthritis (a type of skin and joint condition)

D. If you have moderate to severe Crohn's disease, renewal also requires:
   1. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)

E. If you have moderate to severe ulcerative colitis, renewal also requires:
   1. You will NOT use Steqeyma concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)

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USTEKINUMAB-STBA

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Steqeyma and Stelara.

REFERENCES

Steqeyma [Prescribing Information]. Jersey City, NJ: CELLTRION USA, Inc.; December 2025.
Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; August 2026.

Created: 10/25
Effective: 09/09/26 Client Approval: 09/26 DMC Approval: 09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VADADUSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VADADUSTAT	VAFSEO	49335		GPI-10 (8240258000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has been receiving dialysis for at least 3 months
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient has an eGFR of less than 60 mL/min/1.73m(2) corresponding to stage 3, 4, or 5 chronic kidney disease (CKD)
   - The patient has a hemoglobin level of less than 12 g/dL while treated with an erythropoiesis-stimulating agent (ESA) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa]), and will discontinue ESA therapy prior to starting Vafseo
   - Vafseo will NOT be used concurrently with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (e.g., Jesduvroq [daprodustat]) OR erythropoiesis-stimulating agents (ESAs) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])

   If yes, **approve all strengths for 6 months by GPID or GPI-14 with a quantity limit as follows:**
   - **150mg: #4 per day.**
   - **300mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VADADUSTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VADADUSTAT (Vafseo)** requires the following rule(s) be met for approval:

A. You have anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
B. You are 18 years of age or older
C. You have been receiving dialysis (process of removing excess water, toxins from the blood) for at least 3 months
D. Therapy is prescribed by or in consultation with a nephrologist (a type of kidney doctor)
E. You have an estimated glomerular filtration rate (eGFR: a tool for evaluating kidney function) of less than 60 mL/min/1.73m(2), confirming stage 3, 4, or 5 chronic (long-term) kidney disease (CKD)
F. You have a hemoglobin level (a type of blood test) of less than 12 g/dL while treated with an erythropoiesis-stimulating agent (ESA) (such as Epogen [epoetin alfa], Procrit [epoetin alfa]), and you will discontinue ESA therapy before starting Vafseo
G. You will NOT use Vafseo concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Jesduvroq [daprodustat]) OR erythropoiesis-stimulating agents (ESAs) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VADADUSTAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of anemia due to chronic kidney disease (CKD) (ICD-10 D63.1) and meet **ALL** of the following criteria?
   - The patient has a hemoglobin level of at least 10 g/dL OR the patient's hemoglobin level has increased by at least 2 g/dL from their baseline level
   - Vafseo will NOT be used concurrently with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (e.g., Jesduvroq [daprodustat]) OR erythropoiesis-stimulating agents (ESAs) (e.g., Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with a quantity limit as follows:**
   - **150mg: #4 per day.**
   - **300mg: #2 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VADADUSTAT (Vafseo)** requires the following rule(s) be met for renewal:
   A. You have anemia (a type of blood condition) due to chronic (long-term) kidney disease (CKD)
   B. You have a hemoglobin level (a type of blood test) of at least 10 g/dL OR your hemoglobin level has increased by at least 2 g/dL from your baseline level (before treatment)
   C. You will NOT use Vafseo concurrently (at the same time) with other hypoxia-inducible factor-prolyl hydroxylase inhibitors (HIF-PHIs) (such as Jesduvroq [daprodustat]) OR erythropoiesis-stimulating agents (ESAs) (such as Epogen [epoetin alfa], Procrit [epoetin alfa], Retacrit [epoetin alfa-epbx], Aranesp [darbepoetin alfa], Mircera [methoxy polyethylene glycol-epoetin beta])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vafseo.

REFERENCES

Vafseo [Prescribing Information]. Cambridge, MA: Akebia Therapeutics, Inc.; March 2024.

Created: 07/24
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VALBENAZINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VALBENAZINE TOSYLATE	INGREZZA	44202		GPI-10 (6238008020)	

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?
   - Tardive dyskinesia (TD) (ICD-10 G24.01)
   - Chorea associated with Huntington's disease (ICD-10 G10)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a history of using a dopamine antagonist (e.g., haloperidol, ziprasidone, metoclopramide) for at least 12 months?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VALBENAZINE (Ingrezza)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You have tardive dyskinesia (TD: uncontrolled body movements)
      2. You have chorea (involuntary muscle movements) associated with Huntington's disease (a type of brain disorder)
      3. You have a history of using a dopamine antagonist (a type of medication such as haloperidol, ziprasidone, metoclopramide) for at least 12 months

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ingrezza.

REFERENCES

Ingrezza [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc; February 2025.

Created: 04/17
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 01/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VAMOROLONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VAMOROLONE	AGAMREE	49283		GPI-10 (2210007500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01) and meet **ALL** of the following criteria?
   - The patient is 2 years of age and older
   - Therapy is prescribed by or in consultation with a neurologist specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
   - The patient's diagnosis of DMD is confirmed by genetic testing

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient tried prednisone or prednisolone for at least 6 months?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Did the patient experience lack of efficacy with prednisone or prednisolone and meet **ALL** of the following criteria?
   - The patient is not in Stage 1 of the disease (the pre-symptomatic phase)
   - Steroid myopathy has been ruled out
   - The patient has experienced deterioration in ambulation, functional status, or pulmonary function while on prednisone or prednisolone that is consistent with advancing disease (stage 2 or higher) and assessed using standard measures over time (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time, 10-meter run/walk time, North Star Ambulatory Assessment [NSAA])

   If yes, **approve for 6 months by HICL with a quantity limit of #7.69mL per day.**
   If no, continue to #4.

4. Did the patient experience a significant adverse effect (e.g., weight gain) on prednisone or prednisolone that is negatively impacting a comorbid condition (e.g., diabetes)?

   If yes, **approve for 6 months by HICL with a quantity limit of #7.69mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VAMOROLONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for approval:

A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
B. You are 2 years of age and older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve system doctor) specializing in the treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
D. Your diagnosis of DMD is confirmed by genetic testing
E. You have tried prednisone or prednisolone for at least 6 months
F. You meet ONE of the following:
    1. Prednisone or prednisolone did not work for you, and you meet ALL of the following:
        a. You are not in Stage 1 of the disease (the pre-symptomatic phase)
        b. There is no steroid myopathy (muscle disease due to steroid use)
        c. You have experienced a decrease in ambulation (walking), functional status, or pulmonary (lung) function, while treated with prednisone or prednisolone, that is consistent with advancing disease (stage 2 or higher) and that is assessed by standard measures over time (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor, 10-meter run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
    2. You have experienced a significant adverse effect (side effects such as weight gain) on prednisone or prednisolone that is negatively impacting a co-existing comorbid condition (such as diabetes [a disorder with high blood sugar])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VAMOROLONE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) (ICD-10 G71.01)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the patient currently ambulatory **AND** meets the following criterion?
   - The patient has shown improvement while on Agamree, as assessed by a standard set of ambulatory or functional status measures (e.g., 6-minute walking distance [6MWD], ascending or descending 4 stairs, rise from floor time [Gower's maneuver], 10-meter (30 feet) run/walk time, North Star Ambulatory Assessment [NSAA])

   If yes, **approve for 12 months by HICL with a quantity limit of #7.69mL per day.**
   If no, continue to #3.

3. Is the patient currently non-ambulatory **AND** meets the following criterion?
   - The patient has maintained or demonstrated a less than expected decline in pulmonary function or upper limb strength while on Agamree, as assessed by standard measures (e.g., pulmonary function [FVC, PFTs], upper limb strength)

   If yes, **approve for 12 months by HICL with a quantity limit of #7.69mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VAMOROLONE (Agamree)** requires the following rules be met for renewal:
   A. You have Duchenne muscular dystrophy (DMD: a type of muscle disorder)
   B. If you are currently ambulatory (can walk), approval also requires:
      1. You have shown improvement while on Agamree as measured by a standard set of ambulatory or functional status measures (such as, the 6-minute walking distance [6MWD], going up or down 4 stairs, time to rise from the floor [Gower's maneuver], 10-meter (30 feet) run/walk time, North Star Ambulatory Assessment [NSAA: a tool for evaluating Duchenne muscular dystrophy])
   C. If you are currently non-ambulatory (cannot walk), approval also requires:
      1. You have maintained or had a less than expected decrease in pulmonary (lung) function or upper limb strength while on Agamree as assessed by standard measures (such as pulmonary function [forced vital capacity, pulmonary function tests], upper limb strength)

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VAMOROLONE

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Agamree.

REFERENCES

Agamree [Prescribing Information]. Burlington, MA: Santhera Pharmaceuticals, Inc.; June 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 01/24
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 10/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VANDETANIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VANDETANIB	CAPRELSA	37531		GPI-10 (2153308500)	

GUIDELINES FOR USE

1. Is the patient currently stable on the requested medication?

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **100mg: #2 per day.**
   - **300mg: #1 per day.**

   If no, continue to #2.

2. Does the patient have diagnosis of symptomatic or progressive medullary thyroid cancer (ICD-10 C73) AND meet the following criterion?
   - The patient's cancer is unresectable locally advanced or metastatic disease

   If yes, **approve for 12 months by GPID or GPI-14 as follows:**
   - **100mg: #2 per day.**
   - **300mg: #1 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline for **VANDETANIB (Caprelsa)** requires **ONE** of the following rule(s) be met for approval:
   A. You are currently stable on the requested medication
   B. You have symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease (advanced thyroid cancer that cannot be removed with surgery and has spread to nearby tissue, lymph nodes, or other parts of the body)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VANDETANIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Caprelsa.

REFERENCS

Caprelsa [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP. March 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 05/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 11/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VANZACAFTOR/ TEZACAF/ DEUTIVACAF	ALYFTREK	50120		GPI-10 (4530990385)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
   - Alyftrek will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
   - The patient has at least ONE variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is either responsive to Alyftrek based on clinical or in vitro data or that results in the production of CFTR protein

   If yes, **approve all strengths for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **4-20-50mg: #3 per day.**
   - **10-50-125mg: #2 per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (Alyftrek)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: a type of lung disorder)
B. You are 6 years of age or older
C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You will NOT use Alyftrek concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as a type of medication containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)
E. You have at least ONE variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (a type of gene) that is either responsive to Alyftrek based on clinical or in vitro data (testing outside of the body in a tube) or that results in the production of CFTR protein

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) (ICD-10 Group E84) and meet ALL of the following criteria?
   - The patient has experienced an improvement in clinical status
   - Alyftrek will NOT be used concurrently with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (e.g., medications containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

   If yes, **approve all strengths for lifetime by GPID or GPI-14 with the following quantity limits:**
   - **4-20-50mg: #3 per day.**
   - **10-50-125mg: #2 per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VANZACAFTOR-TEZACAFTOR-DEUTIVACAFTOR (Alyftrek)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (CF: a type of lung disorder)
   B. You have experienced an improvement in your clinical status
   C. You will NOT use Alyftrek concurrently (at the same time) with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator (such as a type of medication containing vanzacaftor, deutivacaftor, ivacaftor, lumacaftor, tezacaftor, or elexacaftor)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alyftrek.

REFERENCES

Alyftrek [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; March 2026.

Created: 01/25
Effective: 05/09/26 Client Approval: 05/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VARENICLINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VARENICLINE TARTRATE	TYRVAYA		51384	GPI-10 (8628008020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of dry eye disease (ICD-10 Group H04.12) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with an ophthalmologist or optometrist
   - The patient has at least ONE positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test)

   If yes, **approve for 3 months by GPID or GPI-10 with a quantity limit of #8.4mL per 30 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for approval:
   A. You have dry eye disease (DED: a type of eye condition)
   B. Therapy is prescribed by or in consultation with an ophthalmologist or optometrist (types of eye doctors)
   C. You have at least ONE positive diagnostic test (such as tear breakup time, tear film osmolarity, ocular surfacing staining, Schirmer test)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VARENICLINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of dry eye disease (ICD-10 Group H04.12) **AND** meet the following criterion?
   - The patient has demonstrated improvement of dry eye disease

   If yes, **approve for 12 months by GPID or GPI-10 with a quantity limit of #8.4mL per 30 days.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VARENICLINE (Tyrvaya)** requires the following rule(s) be met for renewal:
   A. You have dry eye disease (DED: a type of eye condition)
   B. You have demonstrated improvement of dry eye disease (the treatment is working)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyrvaya.

REFERENCES

Tyrvaya [Prescribing Information]. Princeton, NJ: Oyster Point Pharma, Inc.; February 2024.

Created: 10/21
Effective: 08/11/25 Client Approval: 07/25 P&T Approval: 07/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEDOLIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VEDOLIZUMAB	ENTYVIO	41146		GPI-10 (5250308000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the 300 mg vial for 1 month with a quantity limit of #2.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of ONE WEEK after the last date of the first approval):**
     - **300 mg vial: #1 per 56 days.**
     - **108 mg/0.68 mL pen: #1.36 mL per 28 days.**

   If no, continue to #2.

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INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a gastroenterologist
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for a total of 6 months by GPID or GPI-14. Please enter two authorizations as follows:**
   - **FIRST APPROVAL: Approve the 300 mg vial for 1 month with a quantity limit of #2.**
   - **SECOND APPROVAL: Approve the requested strength for 5 months as follows (enter a start date of ONE WEEK after the last date of the first approval):**
     - **300 mg vial: #1 per 56 days.**
     - **108 mg/0.68 mL pen: #1.36 mL per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VEDOLIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe Crohn's disease, approval also requires:
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
   3. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz)
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

(Initial denial text continued on next page)

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VEDOLIZUMAB

INITIAL CRITERIA (CONTINUED)

C. If you have moderate to severe ulcerative colitis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions)
3. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
4. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Skyrizi (risankizumab-rzaa)
   c. Tremfya (guselkumab)
   d. Omvoh (mirikizumab-mrkz)
   e. Adalimumab-ryvk/adalimumab-aaty
   f. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
   g. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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VEDOLIZUMAB

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) (ICD-10 Group K50) and meet **ALL** of the following criteria?
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of CD
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

   [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
   - **300 mg vial: #1 per 56 days.**
   - **108 mg/0.68 mL pen: #1.36 mL per 28 days.**

   If no, continue to #2.

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VEDOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) (ICD-10 Group K51) and meet **ALL** of the following criteria?
   - Entyvio will NOT be used concurrently with another systemic biologic (e.g., Humira [adalimumab]) or targeted small molecules (e.g., JAK inhibitor [e.g., Rinvoq (upadacitinib)], PDE-4 inhibitor) for the treatment of UC
   - The patient had a trial of or contraindication to TWO of the following preferred agents:
     - Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
     - Skyrizi (risankizumab-rzaa)
     - Tremfya (guselkumab)
     - Omvoh (mirikizumab-mrkz)
     - Adalimumab-ryvk/adalimumab-aaty
     - Xeljanz (tofacitinib IR or XR) (**NOTE:** Xeljanz requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])
     - Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response or intolerance to a TNF blocker [e.g., adalimumab-ryvk/adalimumab-aaty])

     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve the requested strength for 12 months by GPID or GPI-14 as follows:**
     - **300 mg vial: #1 per 56 days.**
     - **108 mg/0.68 mL pen: #1.36 mL per 28 days.**

     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

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VEDOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **VEDOLIZUMAB (Entyvio)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: a type of bowel disorder)
   2. Moderate to severe ulcerative colitis (UC: a type of digestive disorder)

B. If you have moderate to severe Crohn's disease, renewal also requires:
   1. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of Crohn's disease (a type of bowel disorder)
   2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
      a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
      b. Skyrizi (risankizumab-rzaa)
      c. Tremfya (guselkumab)
      d. Omvoh (mirikizumab-mrkz)
      e. Adalimumab-ryvk/adalimumab-aaty
      f. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

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VEDOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

C. If you have moderate to severe ulcerative colitis, renewal also requires:

1. You will NOT use Entyvio concurrently (at the same time) with another systemic biologic (such as Humira [adalimumab]) or targeted small molecules (such as JAK [Janus kinase] inhibitor [such as Rinvoq (upadacitinib)], PDE-4 [phosphodiesterase-4] inhibitor) for the treatment of ulcerative colitis (a type of digestive disorder)
2. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications:
   a. Yesintek (ustekinumab-kfce)/ustekinumab-aekn/Steqeyma (ustekinumab-stba)
   b. Skyrizi (risankizumab-rzaa)
   c. Tremfya (guselkumab)
   d. Omvoh (mirikizumab-mrkz)
   e. Adalimumab-ryvk/adalimumab-aaty
   f. Xeljanz (tofacitinib immediate-release or extended-release) (**NOTE:** Xeljanz requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])
   g. Rinvoq (upadacitinib) (**NOTE:** Rinvoq requires additional criteria of inadequate response [medication did not work] or intolerance [side effect] to a tumor necrosis factor [TNF] blocker [such as adalimumab-ryvk/adalimumab-aaty])

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Entyvio.

REFERENCES

Entyvio [Prescribing Information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; February 2026.

Created: 05/14
Effective: 07/01/26 Client Approval: 06/26 P&T Approval: 01/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VELAGLUCERASE ALFA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VELAGLUCERASE ALFA	VPRIV	36874		GPI-10 (8270008510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease (ICD-10 E75.22) and meet the following criteria?
   - The patient is 4 years of age or older
   - The patient had a trial of or contraindication to Elelyso

   If yes, **approve for up to 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VELAGLUCERASE ALFA (Vpriv)** requires the following rule(s) be met for approval:
   A. You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
   B. You are 4 years of age or older
   C. You had a trial of or contraindication to (harmful for you to use) Elelyso

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vpriv.

REFERENCES

Vpriv [Prescribing Information]. Lexington, MA: Shire Human Genetic Therapies, Inc.; September 2024.

Created: 05/05
Effective: 02/09/26 Client Approval: 01/26 P&T Approval: 05/15

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VELMANASE ALFA-TYCV (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VELMANASE ALFA-TYCV	LAMZEDE	46263		GPI-10 (3090238070)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-central nervous system manifestations of alpha-mannosidosis?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VELMANASE ALFA-TYCV (Lamzede)** requires the following rule(s) be met for approval:
   A. You have non-central nervous system manifestations (symptoms outside of the brain and spinal cord) of alpha-mannosidosis (a rare genetic condition)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Lamzede.

REFERENCES
Lamzede [Prescribing Information]. Cary, NC: Chiesi USA, Inc.; February 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 04/23
Client Approval: 05/23
P&T Approval:04/23

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEMURAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VEMURAFENIB	ZELBORAF	37837		GPI-10 (2153208000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma (ICD-10 Group C43) and meet **ALL** of the following criteria?
   - The patient has a BRAF V600E mutation as detected by an FDA-approved test
   - Zelboraf will be used alone or in combination with Cotellic (cobimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Erdheim-Chester Disease (E88.89) **AND** meet the following criterion?
   - The patient has a BRAF V600 mutation

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VEMURAFENIB (Zelboraf)** requires the following rules be met for approval:
   A. You have ONE of the following:
      1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be completely removed with surgery or has spread to other parts of the body)
      2. Erdheim-Chester Disease (a type of multisystem mutation)

   B. If you have unresectable or metastatic melanoma, approval also requires:
      1. You have a BRAF V600E mutation (a type of abnormal change in a gene) as detected by a Food and Drug Administration (FDA)-approved test
      2. Zelboraf will be used alone or in combination with Cotellic (cobimetinib)

   C. If you have Erdheim-Chester Disease, approval also requires:
      1. You have a BRAF V600 mutation (a type of abnormal change in a gene)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VEMURAFENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zelboraf.

REFERENCES

Zelboraf [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Created: 08/11
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 04/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VENETOCLAX

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VENETOCLAX	VENCLEXTA	43284		GPI-10 (2147008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) OR small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **Starting Pack: #42 (1 pack) per 28 days.**
   - **10mg: #2 per day.**
   - **50mg: #1 per day.**
   - **100mg: #4 per day.**

   If no, continue to #2.

2. Does the patient have acute myeloid leukemia (AML) (ICD-10 Group C92.0) **AND** meet the following criterion?
   - The patient is newly diagnosed (e.g., starting or previously started Venclexta treatment at the time of diagnosis)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient is 75 years of age or older
   - The patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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VENETOCLAX

GUIDELINES FOR USE (CONTINUED)

4. Will Venclexta be used in combination with azacitidine, decitabine, or Inqovi (decitabine/cedazuridine)?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **10mg: #2 per day.**
   - **50mg: #1 per day.**
   - **100mg: #4 per day.**

   If no, continue to #5.

5. Will Venclexta be used in combination with low-dose cytarabine?

   If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**
   - **10mg: #2 per day.**
   - **50mg: #1 per day.**
   - **100mg: #6 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VENETOCLAX (Venclexta)** requires that the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      2. Small lymphocytic lymphoma (SLL: a type of blood cancer)
      3. Acute myeloid leukemia (AML: a type of blood and bone marrow cancer)

   B. If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
      1. You are 18 years of age or older

   C. If you have acute myeloid leukemia, approval also requires:
      1. You are newly diagnosed (such as you are starting or previously started Venclexta treatment at the time your condition was identified)
      2. Venclexta will be used in combination with azacitidine, decitabine, Inqovi (decitabine/cedazuridine), or low-dose cytarabine
      3. You meet ONE of the following:
         a. You are 75 years of age or older
         b. You are 18 years of age or older with comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (a type of therapy to treat cancer)

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VENETOCLAX

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Venclexta and Inqovi.

REFERENCES

Venclexta [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; May 2026.
Inqovi [Prescribing Information]. Pleasanton, CA: Astex Pharmaceuticals, Inc.; May 2026.

Created: 11/16
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEPDEGESTRANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VEPDEGESTRANT	VEPPANU	51300		GPI-10 (2140378000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's cancer is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor-1 (ESR1) gene mutation(s), as detected by an FDA- authorized test
   - The patient has had disease progression following at least ONE line of endocrine therapy (e.g., anastrozole, letrozole)
   - Therapy is prescribed by or in consultation with an oncology specialist
   - Veppanu will NOT be used concurrently with another selective estrogen receptor degrader (SERD) (e.g., Orserdu [elacestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   INITIAL DENIAL TEXT:

   Our guideline named **VEPDEGESTRANT (Veppanu)** requires the following rule(s) be met for approval:
   A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. Your cancer is estrogen receptor (ER: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test
   C. You have had disease progression (worsening) following at least ONE line of endocrine therapy (a type of hormone therapy such as anastrozole, letrozole)
   D. Therapy is prescribed by or in consultation with an oncology specialist (a type of cancer doctor)
   E. You will NOT use Veppanu concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Orserdu [elacestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

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VEPDEGESTRANT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced or metastatic breast cancer (ICD-10 Group C50) and meet **ALL** of the following criteria?
   - The patient's cancer is estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative with estrogen receptor-1 (ESR1) gene mutation(s), as detected by an FDA- authorized test
   - The patient has demonstrated clinical benefit while on therapy as shown by a partial or complete response OR stable disease
   - Veppanu will NOT be used concurrently with another selective estrogen receptor degrader (SERD) (e.g., Orserdu [elacestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT:

   Our guideline named **VEPDEGESTRANT (Veppanu)** requires the following rule(s) be met for renewal:
   A. You have advanced or metastatic breast cancer (a type of cancer that has spread from where it started to nearby tissue or lymph nodes or to other parts of the body)
   B. Your cancer is estrogen receptor (ER: a type of protein)-positive, human epidermal growth factor receptor 2 (HER2: a type of protein)-negative with estrogen receptor-1 (ESR1) gene mutation(s) (abnormal changes in a type of gene), as detected by a Food and Drug Administration (FDA)-authorized test
   C. You have experienced clinical benefit while on therapy as shown by a partial (cancer has shrunk but did not go away) or complete response (cancer went away completely) OR stable disease (disease has stopped growing or spreading)
   D. You will NOT use Veppanu concurrently (at the same time) with a selective estrogen receptor degrader (SERD: a type of hormone therapy such as Orserdu [elacestrant], Faslodex [fulvestrant], Inluriyo [imlunestrant])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Veppanu.

REFERENCES

Veppanu [Prescribing Information]. New Haven, CT: Arvinas Operations, Inc.; May 2026.

Created: 08/26
Effective: 09/01/26 DMC Approval: 08/18/2

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VERICIGUAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VERICIGUAT	VERQUVO	47075		GPI-10 (4090008500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic heart failure (HF) (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has an ejection fraction of less than 45 percent
   - Therapy is prescribed by or in consultation with a cardiologist
   - Verquvo will NOT be used concurrently with Adempas (riociguat) or PDE-5 inhibitors (e.g. vardenafil, tadalafil)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a history of and will continue on, or has a contraindication to **ONE** agent from EACH of the following Guideline-Directed Medical Therapy (GDMT) medication classes?
   - ACE inhibitor (e.g., enalapril, lisinopril), ARB (e.g., valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., Entresto [sacubitril/valsartan])
   - Beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate)
   - Aldosterone antagonist (spironolactone or eplerenone)
   - SGLT2 inhibitor indicated for heart failure (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin], Inpefa [sotagliflozin])

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the patient high-risk with worsening heart failure, as evidenced by a hospitalization for heart failure or requirement for intravenous (IV) diuretics?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VERICIGUAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for approval:

A. You have chronic heart failure (HF: a type of heart condition)
B. You are 18 years of age or older
C. You have an ejection fraction (heart function) of less than 45 percent
D. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
E. You will NOT use Verquvo concurrently (at the same time) with Adempas (riociguat) or phosphodiesterase-5 (PDE-5) inhibitors (such as vardenafil, tadalafil)
F. You have tried and will continue use, or you have a contraindication to (harmful for you to use) ONE medication from EACH of the following Guideline-Directed Medical Therapy (GDMT: a type of medical treatment) medication classes:
    1. Angiotensin converting enzyme (ACE) inhibitor (such as enalapril, lisinopril), angiotensin II receptor blocker (ARB) (such as valsartan, candesartan), or angiotensin receptor- neprilysin inhibitor (ARNI) (such as Entresto [sacubitril/valsartan])
    2. Beta-blocker (such as bisoprolol, carvedilol, metoprolol succinate)
    3. Aldosterone antagonist (spironolactone or eplerenone)
    4. Sodium-glucose transporter-2 (SGLT2) inhibitor indicated for heart failure (a type of heart condition) (such as Farxiga [dapagliflozin], Jardiance [empagliflozin], Inpefa [sotagliflozin])
G. You are high-risk with worsening heart failure (a type of heart condition), as shown by hospitalization for heart failure or the need for intravenous (IV: injection into the veins) diuretics (type of medication)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VERICIGUAT

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic heart failure (HF) (ICD-10 Group I50) and meet **ALL** of the following criteria?
   - The patient has an ejection fraction of less than 45 percent
   - Therapy is prescribed by or in consultation with a cardiologist
   - Verquvo will NOT be used concurrently with Adempas (riociguat) or PDE-5 inhibitors (e.g. vardenafil, tadalafil)

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have a history of and will continue on, or has a contraindication to **ONE** agent from EACH of the following Guideline-Directed Medical Therapy (GDMT) medication classes?
   - ACE inhibitor (e.g., enalapril, lisinopril), ARB (e.g., valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI) (e.g., Entresto [sacubitril/valsartan])
   - Beta-blocker (e.g., bisoprolol, carvedilol, metoprolol succinate)
   - Aldosterone antagonist (spironolactone or eplerenone)
   - SGLT2 inhibitor indicated for heart failure (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin], Inpefa [sotagliflozin])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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VERICIGUAT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VERICIGUAT (Verquvo**) requires the following rule(s) be met for renewal:

A. You have chronic heart failure (a type of heart condition)
B. You have an ejection fraction (heart function) of less than 45 percent
C. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor)
D. You will NOT use Verquvo concurrently (at the same time) with Adempas (riociguat) or phosphodiesterase-5 (PDE-5) inhibitors (such as vardenafil, tadalafil)
E. You have tried and will continue use, or you have a contraindication to (harmful for you to use) ONE medication from EACH of the following Guideline-Directed Medical Therapy (GDMT: a type of medical treatment) medication classes:
    1. Angiotensin converting enzyme (ACE) inhibitor (such as enalapril, lisinopril), angiotensin II receptor blocker (ARB) (such as valsartan, candesartan), or angiotensin receptor- neprilysin inhibitor (ARNI) (such as Entresto [sacubitril/valsartan])
    2. Beta-blocker (such as bisoprolol, carvedilol, metoprolol succinate)
    3. Aldosterone antagonist (spironolactone or eplerenone)
    4. Sodium-glucose transporter-2 (SGLT2) inhibitor indicated for heart failure (a type of heart condition) (such as Farxiga [dapagliflozin], Jardiance [empagliflozin], Inpefa [sotagliflozin])

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verquvo.

REFERENCES

Verquvo [Prescribing Information]. Rahway, NJ: Merck Sharp & Dohme LLC; May 2023.

Created: 02/21
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VESTRONIDASE ALFA-VJBK (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VESTRONIDASE ALFA-VJBK	MEPSEVII	44653		GPI-10 (3090768020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or given in consultation with a physician specializing in genetic or metabolic disorders
   - The patient has a documented urinary GAG (glycosaminoglycan) level of greater than three times the upper level of normal based on the laboratory assay
   - MPS VII diagnosis confirmed by documentation of beta-glucuronidase enzyme activity deficiency or genetic testing
   - The patient has at least one of the following clinical signs of MPS VII: enlarged liver and spleen, joint limitations, airway obstructions or pulmonary dysfunction
   - The patient has NOT undergone successful bone marrow or stem cell treatment for MPS VII
   - The patient has limitation in mobility, but remains sufficiently ambulatory for the six-minute walk test (6MWT) to be measured and evaluated

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the patient has improved, maintained, or demonstrated less than expected decline in ambulatory ability based on 6MWT compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires the following rule(s) be met for approval:
   A. You have Mucopolysaccharidosis VII (MPS VII, Sly syndrome: genetic metabolism disorder that does not allow the body to break down a certain chemical)
   B. The requested medication is prescribed by or given in consultation with a physician specializing in genetic or metabolic disorders
   C. You have a documented urinary GAG (glycosaminoglycan: type of chemical that builds up when your body cannot break it down) level of greater than three times the upper level of normal based on the laboratory test
   D. Your diagnosis of Mucopolysaccharidosis VII is confirmed by documentation of beta-glucuronidase enzyme activity deficiency (you don't have a protein that breaks down a chemical) or genetic testing

   (Initial denial text continued on next page.)

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VESTRONIDASE ALFA-VJBK (NSA)

INITIAL CRITERIA (CONTINUED)

E. You have at least ONE of the following clinical signs of Mucopolysaccharidosis VII:
   1. Enlarged liver and spleen
   2. Joint limitations
   3. Airway obstructions or pulmonary (lung/breathing) dysfunction

F. You have not undergone successful bone marrow or stem cell treatment for Mucopolysaccharidosis VII

G. You have limitation in mobility, but you still have ambulatory (walking) capacity for the six-minute walk test (6MWT) to be measured and evaluated

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) **AND** meet the following criterion?

- Patient has improved, maintained, or demonstrated less than expected decline in ambulatory ability based on 6MWT compared to baseline

If yes, **approve for 12 months by HICL or GPI-10.**
If no, do not approve.
RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires the following rule(s) be met for renewal:

A. You have Mucopolysaccharidosis VII (MPS VII, Sly syndrome: genetic metabolism disorder that does not allow the body to break down a certain chemical)

B. You have improved, maintained, or demonstrated less than expected decline in ambulatory (walking) ability based on a six-minute walk test compared to baseline

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VESTRONIDASE ALFA-VJBK (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mepsevii.

REFERENCES

Mepsevii [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc. November 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 03/18
Client Approval: 05/20
P&T Approval: 04/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VIGABATRIN	SABRIL, VIGABATRIN, VIGADRONE, VIGPODER		64315 64314	GPI-14 (72170085000320, 72170085003020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of refractory complex partial seizures (CPS) (ICD-10 Group G40.2) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - The requested medication will be used as adjunctive therapy
   - The potential benefits outweigh the potential risk of vision loss
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to THREE antiepileptic medications, at least two of which must be generic (e.g., carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam IR/ER, gabapentin, zonisamide, topiramate, lamotrigine)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day for all formulations: tablet and powder packet.**

   If no, continue to #2.

2. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) and meet **ALL** of the following criteria?
   - The patient is 1 month to 2 years of age
   - The requested medication will be used as monotherapy
   - The potential benefits outweigh the potential risk of vision loss
   - Therapy is prescribed by or in consultation with a neurologist

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day for the powder packet.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VIGABATRIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VIGABATRIN (Sabril, Vigadrone, Vigpoder)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Refractory complex partial seizures (a type of seizure)
   2. Infantile spasms (a type of seizure disorder in infancy and childhood)

B. If you have refractory complex partial seizures, approval also requires:
   1. You are 2 years of age or older
   2. The requested medication will be used as adjunctive (add-on) therapy
   3. The potential benefits outweigh the potential risk of vision loss
   4. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   5. You have tried or have a contraindication to (harmful for you to use) THREE antiepileptic medications, at least two of which must be generic (medications used to treat seizures such as carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide, topiramate, lamotrigine)

C. If you have infantile spasms, approval also requires:
   1. You are 1 month to 2 years of age
   2. The requested medication will be used as monotherapy (one drug treatment)
   3. The potential benefits outweigh the potential risk of vision loss
   4. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VIGABATRIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of refractory complex partial seizures (CPS) (ICD-10 Group G40.2)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day for all formulations: tablet and powder packet.**

   If no, continue to #2.

2. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) **AND** meet the following criterion?
   - The patient is 1 month to 2 years of age

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #6 per day for the powder packet.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VIGABATRIN (Sabril, Vigadrone, Vigpoder)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Refractory complex partial seizures (a type of seizure)
      2. Infantile spasms (a type of seizure disorder in infancy and childhood)

   B. If you have infantile spasms, renewal also requires:
      1. You are 1 month to 2 years of age

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VIGABATRIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sabril, Vigadrone, and Vigpoder.

REFERENCES

Sabril [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals; October 2021.
Vigadrone [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC.; January 2024.
Vigpoder [Prescribing Information]. Parsippany, NJ: Pyros Pharmaceuticals, Inc; July 2023.

Created: 05/22
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN SOLUTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VIGABATRIN	VIGAFYDE		55889	GPI-14 (72170085002020)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) and meet **ALL** of the following criteria?
   - The patient is 1 month to 2 years of age
   - Vigafyde will be used as monotherapy
   - The potential benefits outweigh the potential risk of vision loss
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient had a trial of or contraindication to generic vigabatrin powder for solution

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30mL per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VIGABATRIN SOLUTION (Vigafyde)** requires the following rule(s) be met for approval:
   A. You have infantile spasms (a type of seizure disorder in infancy and childhood)
   B. You are 1 month to 2 years of age
   C. Vigafyde will be used as monotherapy (one medication treatment)
   D. The potential benefits outweigh the potential risk of vision loss
   E. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
   F. You have tried or have a contraindication to (harmful for you to use) generic vigabatrin powder for solution

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIGABATRIN SOLUTION

RENEWAL CRITERIA

1. Does the patient have a diagnosis of infantile spasms (ICD-10 Group G40.82) **AND** meet the following criterion?
   - The patient is 1 month to 2 years of age

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VIGABATRIN SOLUTION (Vigafyde)** requires the following rule(s) be met for renewal:
   A. You have infantile spasms (a type of seizure disorder in infancy and childhood)
   B. You are 1 month to 2 years of age

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vigafyde.

REFERENCES

Vigafyde [Prescribing Information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; February 2025.

Created: 08/24
Effective: 10/01/25 Client Approval: 08/25 P&T Approval: 07/25

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VILOBELIMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VILOBELIMAB	GOHIBIC	48837		GPI-10 (8580528000)	

GUIDELINES FOR USE

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

    If yes, **do not approve**.
    NOTE: This indication is for hospital use only.

    If no, guideline does not apply.

    DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

    Our guideline named **VILOBELIMAB (Gohibic)** will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults.

    Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gohibic.

REFERENCES

Gohibic [Prescribing Information]. Jena, Germany: InflaRx GmbH, Inc.; May 2023.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 08/23
Client Approval: 08/23
P&T Approval: 07/23

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VILTOLARSEN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VILTOLARSEN	VILTEPSO	46773		GPI-10 (7460008000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) and meets **ALL** of the following criteria?
   - The patient has documentation of genetic testing that confirms mutation in the DMD gene is amenable to exon 53 skipping
   - Therapy is prescribed by or given in consultation with a neurologist specializing in treatment of DMD at a DMD treatment center
   - The patient is ambulatory
   - The patient is currently receiving treatment with or has a contraindication to corticosteroids (e.g., prednisone or prednisolone)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 fill per 7 days. APPROVAL TEXT:** Renewal requires the patient has maintained or demonstrated less than expected decline in ONE of the following: 1) ambulatory ability based on muscle function assessments (e.g., 6-minute walk test), or 2) other muscle function (i.e. pulmonary or cardiac function).

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VILTOLARSEN (Viltepso)** requires the following rule(s) be met for approval:
   A. You have Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)
   B. You have documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in the DMD gene that is responsive to exon 53 skipping (a process that allows a protein to still function with sections of faulty genetic code)
   C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
   D. You are ambulatory (able to move and walk)
   E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)

   (Initial denial text continued on next page)

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VILTOLARSEN (NSA)

INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient meet **ONE** of the following criteria?
   - The patient has maintained or demonstrated less than expected decline in ambulatory ability based on muscle function assessments (e.g., 6-minute walk test)
   - The patient has maintained or demonstrated less than expected decline in other muscle function (i.e. pulmonary or cardiac function)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 fill per 7 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VILTOLARSEN (Viltepso)** requires ONE of the following rule(s) be met for renewal:
   A. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
   B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VILTOLARSEN (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Viltepso.

REFERENCES

Viltepso [Prescribing Information]. Paramus, NJ: NS Pharma, Inc.; August 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 01/01/21
Created: 11/20
Client Approval: 11/20
P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VIMSELTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VIMSELTINIB	ROMVIMZA	50284		GPI-10 (2153178000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) (ICD-10 D48.1; Group M12.2) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Surgical resection of the tumor may cause worsening functional limitation or severe morbidity

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VIMSELTINIB (Romvimza)** requires the following rule(s) be met for approval:
   A. You have symptomatic tenosynovial giant cell tumor (TGCT: a type of tumor that affects joints)
   B. You are 18 years of age or older
   C. Surgical resection (removal by surgery) of the tumor may cause worsening functional limitation or severe morbidity (illness)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Romvimza.

REFERENCES

Romvimza [Prescribing Information]. Waltham, MA: Deciphera Pharmaceuticals, LLC; February 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VISMODEGIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VISMODEGIB	ERIVEDGE	38455		GPI-10 (2137007000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic basal cell carcinoma (ICD-10 C44.01, C44.41, C44.81, C44.91; Groups C44.11, C44.21, C44.31, C44.51, C44.61, C44.71) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced basal cell carcinoma (ICD-10 C44.01, C44.41, C44.81, C44.91; Groups C44.11, C44.21, C44.31, C44.51, C44.61, C44.71) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer has recurred following surgery OR the patient is not a candidate for surgery or radiation

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VISMODEGIB (Erivedge)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. Metastatic basal cell carcinoma (a type of skin cancer that has spread to other parts of the body)
      2. Locally advanced basal cell carcinoma (a type of skin cancer that has spread from where it started to nearby tissue or lymph nodes)

   B. If you have metastatic basal cell carcinoma, approval also requires:
      1. You are 18 years of age or older

   C. If you have locally advanced basal cell carcinoma, approval also requires:
      1. You are 18 years of age or older
      2. Your cancer has returned after surgery OR you are not a candidate for surgery or radiation

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VISMODEGIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Erivedge.

REFERENCES

Erivedge [Prescribing Information]. South San Francisco, CA: Genentech, Inc., March 2023.

Created: 02/12
Effective: 02/01/26 Client Approval: 04/25 P&T Approval: 01/22

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOCLOSPORIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VOCLOSPORIN	LUPKYNIS	47077		GPI-10 (9940208000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of active lupus nephritis (LN) (ICD-10 M32.14) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lupkynis will be used in combination with a background immunosuppressive therapy regimen (e.g., mycophenolate mofetil, corticosteroids [e.g., prednisone])
   - Therapy is prescribed by or in consultation with a rheumatologist or nephrologist

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for approval:
   A. You have active lupus nephritis (LN: a type of immune condition that affects the kidneys)
   B. You are 18 years of age or older
   C. Lupkynis will be used in combination with a background immunosuppressive therapy regimen (such as mycophenolate mofetil, corticosteroids [such as prednisone])
   D. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor) or nephrologist (a type of kidney doctor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOCLOSPORIN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of active lupus nephritis (LN) (ICD-10 M32.14) **AND** meet the following criterion?
   - The patient has improvement in renal response from baseline laboratory values (i.e., eGFR or proteinuria) and/or clinical parameters (e.g., fluid retention, use of rescue drugs, glucocorticoid use)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6 per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for renewal:
   A. You have active lupus nephritis (LN: a type of immune condition that affects the kidneys)
   B. You have improvement in renal response from baseline laboratory values (estimated glomerular filtration rate [eGFR: a tool for evaluating kidney function] or proteinuria [level of protein in urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, steroid use)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lupkynis.

REFERENCES

Lupkynis [Prescribing Information]. Victoria, BC: Aurinia Pharmaceuticals Inc.; April 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 02/21
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VONOPRAZAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VONOPRAZAN/AMOXICILLIN	VOQUEZNA DUAL PAK	47981		GPI-10 (4999320220)	
VONOPRAZAN/AMOXICILLIN /CLARITH	VOQUEZNA TRIPLE PAK	47983		GPI-10 (4999320320)	
VONOPRAZAN FUMARATE	VOQUEZNA	48007		GPI-10 (4927508710)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of *Helicobacter pylori (H. pylori)* infection (ICD-10 B96.81) **AND** meet the following criterion?
- The patient is 18 years of age or older

If yes, continue to #2.
If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
- The request is for Voquezna 20mg and will be used in combination with amoxicillin
- The request is for Voquezna 20mg and will be used in combination with amoxicillin and clarithromycin
- The request is for Voquezna Dual Pak
- The request is for Voquezna Triple Pak

If yes, **approve for 30 days by HICL or GPI-10 for the requested agent as follows:**
- **20mg: #28 per 14 days for #1 fill (PAC Note: Please override the quantity limit coded on the formulary by selecting the "QL Only" override).**
- **Dual Pak: #1 fill.**
- **Triple Pak: #1 fill.**

If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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VONOPRAZAN

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of erosive esophagitis (ICD-10 Group K20) and meet **ALL** of the following criteria?
   - The request is for Voquezna
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the clinical standard of care agent: ONE proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole) at the maximum dose for 8 weeks

   If yes, **approve for 8 weeks by HICL or GPI-10.**
   If no, continue to #4.

4. Does the patient have a diagnosis of non-erosive gastroesophageal reflux disease (ICD-10 Group K21 except for K21.01) and meet **ALL** of the following criteria?
   - The request is for Voquezna 10mg
   - The patient is 18 years of age or older
   - The patient does not have a previous treatment failure with Voquezna in the last 12 months
   - The patient had a trial of or contraindication to the clinical standard of care agent: ONE proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole) at the maximum dose for 8 weeks

   If yes, **approve for 4 weeks by GPID or GPI-14.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VONOPRAZAN (Voquezna Dual Pak, Voquezna Triple Pak, Voquezna)** requires the following rule(s) be met for approval:
   A. You have ONE of the following:
      1. *Helicobacter pylori (H. pylori*: a type of bacteria*)* infection
      2. Erosive esophagitis (a type of digestive disorder)
      3. Non-erosive gastroesophageal reflux disease (a type of digestive disorder)

(Initial denial text continued on the next page)

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VONOPRAZAN

INITIAL CRITERIA (CONTINUED)

B. If you have a *Helicobacter pylori* infection, approval also requires:
1. You are 18 years of age or older
2. You meet ONE of the following:
   a. Your request is for Voquezna 20mg in combination with amoxicillin
   b. Your request is for Voquezna 20mg in combination with amoxicillin and clarithromycin
   c. Your request is for Voquezna Dual Pak
   d. Your request is for Voquezna Triple Pak

C. If you have erosive esophagitis, approval also requires:
1. Your request is for Voquezna
2. You are 18 years of age or older
3. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole) at a maximum dose for 8 weeks

D. If you have non-erosive gastroesophageal reflux disease, approval also requires:
1. Your request is for Voquezna 10mg
2. You are 18 years of age or older
3. You do not have a previous treatment failure (medication did not work) with Voquezna in the last 12 months
4. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole) at the maximum dose for 8 weeks

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VONOPRAZAN

RENEWAL CRITERIA

NOTE: For the diagnosis of *Helicobacter pylori* (*H. pylori*) infection or non-erosive gastroesophageal reflux disease, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of erosive esophagitis (ICD-10 Group K20) **AND** the request is for Voquezna?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for a continuation of treatment (the patient recently received an initial prior authorization approval for 8 weeks)?

   If yes, continue to #3.
   If no, refer to the Initial Criteria.

3. Has the patient maintained a clinical response while on Voquezna?

   If yes, **approve for 24 weeks by HICL or GPI-10.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VONOPRAZAN (Voquezna)** requires the following rule(s) be met for renewal:
   A. You have erosive esophagitis (a type of digestive disorder)
   B. Your request is for Voquezna
   C. You have maintained a clinical response on Voquezna (the treatment is working)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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VONOPRAZAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voquezna TRIPLE PAK, Voquezna DUAL PAK, and Voquezna.

REFERENCES

Voquezna TRIPLE PAK, Voquezna DUAL PAK [Prescribing Information]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; October 2025.
Voquezna [Prescribing Information]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; July 2024.

Created: 06/22
Effective: 08/27/26 Client Approval: 08/26 P&T Approval: 04/24

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VORASIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VORASIDENIB CITRATE	VORANIGO	49796		GPI-10 (2153518000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Grade 2 astrocytoma or oligodendroglioma (ICD-10 C71.9) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation
   - Voranigo will be used following surgery, including biopsy, sub-total resection, or gross total resection

   If yes, **approve all strengths for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **40mg: #1 per day.**
   - **10mg: #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VORASIDENIB (Voranigo)** requires the following rule(s) be met for approval:
   A. You have Grade 2 astrocytoma or oligodendroglioma (types of brain cancer)
   B. You are 12 years of age or older
   C. Your cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation (abnormal changes in types of genes that increase the risk of certain diseases)
   D. Voranigo will be used following surgery, including biopsy (removal of cells or tissue from the body for examination), sub-total resection (partial removal of tumor), or gross total resection (complete removal of tumor)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VORASIDENIB

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Voranigo.

REFERENCES
Voranigo [Prescribing Information]. Boston, MA: Servier Pharmaceuticals LLC; August 2024.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 09/01/24
Created: 08/24
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VORINOSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VORINOSTAT	ZOLINZA	34070		GPI-10 (2153157500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cutaneous T-cell lymphoma (ICD-10 Group C84.A) **AND** meet the following criterion?
   - The patient has progressive, persistent, or recurrent disease on or following two systemic therapies (e.g. Targretin [bexarotene], Istodax [romidepsin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VORINOSTAT (Zolinza)** requires the following rule(s) be met for approval:
   A. You have cutaneous T-cell lymphoma (a type of blood cancer that affects the skin)
   B. You have progressive (worsening), persistent (continues to exist), or recurrent (returns) disease on or following two systemic therapies (a type of medication that goes to the entire body such as Targretin [bexarotene], Istodax, [romidepsin])

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zolinza.

REFERENCES

Zolinza [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2018.

Created: 05/26
Effective: 07/01/26 Client Approval: 05/26 P&T Approval: 01/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOSORITIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VOSORITIDE	VOXZOGO	47677		GPI-10 (3095008000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of achondroplasia (ICD-10 Q77.4) and meet **ALL** of the following criteria?
   - The patient has open epiphyses
   - Therapy is prescribed by or in consultation with an endocrinologist, orthopedist, or medical geneticist
   - Voxzogo will NOT be used concurrently with another C-type natriuretic peptide (CNP) (e.g., Yuviwel [navepegritide]) for the treatment of achondroplasia

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 vial per day.**
   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOSORITIDE (Voxzogo)** requires the following rule(s) be met for approval:
   A. You have achondroplasia (a type of bone condition)
   B. You have open epiphyses (the end part of a long bone)
   C. Therapy is prescribed by or in consultation with an endocrinologist (a type of hormone doctor), orthopedist (a type of doctor who specializes in bones, joints, muscles, ligaments, tendons and nerves), or medical geneticist (doctor who treats gene disorders)
   D. You will NOT use Voxzogo concurrently (at the same time) with another C-type natriuretic peptide (CNP) (such as Yuviwel [navepegritide]) for the treatment of achondroplasia (a type of bone condition)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VOSORITIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of achondroplasia (ICD-10 Q77.4) and meet **ALL** of the following criteria?
   - The patient has experienced an improvement in annual growth velocity since baseline
   - The patient's epiphyses remain open
   - Voxzogo will NOT be used concurrently with another C-type natriuretic peptide (CNP) e.g., Yuviwel [navepegritide]) for the treatment of achondroplasia

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 vial per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VOSORITIDE (Voxzogo)** requires the following rule(s) be met for renewal:
   A. You have achondroplasia (a type of bone condition)
   B. You have experienced an improvement in annual growth velocity (rate of growth) since baseline (before treatment with Voxzogo)
   C. Your epiphyses (the end part of a long bone) remain open
   D. You will NOT use Voxzogo concurrently (at the same time) with another C-type natriuretic peptide (CNP) (such as Yuviwel [navepegritide]) for the treatment of achondroplasia (a type of bone condition)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Voxzogo.

REFERENCES

Voxzogo [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical, Inc.; November 2024.

Created: 01/22
Effective: 03/18/26 Client Approval: 03/26 P&T Approval: 10/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VUTRISIRAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VUTRISIRAN SODIUM	AMVUTTRA	48059		GPI-10 (6270609010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   - The patient is ambulatory (i.e., Familial Amyloid Polyneuropathy [FAP] stage 1 - 2 OR Polyneuropathy Disability [PND] stage I - IIIb polyneuropathy)
   - Amvuttra will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran])

   If yes, continue to #2.
   If no, continue to #3.

2. Is the patient's diagnosis confirmed by **ONE** of the following?
   - Biopsy of tissue/organ to confirm amyloid presence AND chemical typing to confirm presence of TTR (transthyretin) protein
   - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #0.5mL per 3 months.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
   - The patient has New York Heart Association (NYHA) Class I, II, or III heart failure
   - Amvuttra will NOT be used concurrently with a transthyretin stabilizer (acoramidis [Attruby], tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) for the treatment of ATTR-CM

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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VUTRISIRAN

INITIAL CRITERIA (CONTINUED)

4. Is the patient's diagnosis confirmed by **ONE** of the following?
   - Bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP
     (Note: Strongly positive defined as Grade 2 or 3 uptake using the Perugini Grade 1-3 scoring system)
   - Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence AND chemical typing to confirm presence of transthyretin (TTR) protein

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.5mL per 3 months.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VUTRISIRAN (Amvuttra)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
      2. Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)

   B. If you have hereditary transthyretin-mediated amyloidosis with polyneuropathy, approval also requires:
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nerve doctor), cardiologist (a type of heart doctor), hATTR (a rare genetic disorder with widespread nerve pain/damage) specialist, or medical geneticist (doctor who treats gene disorders)
      3. You are ambulatory (able to walk) (you have Familial Amyloid Polyneuropathy [FAP: a tool used to evaluate disease severity] stage 1 to 2 OR Polyneuropathy Disability [PND: a tool used to evaluate disease severity] stage I to IIIb polyneuropathy)
      4. You will NOT use Amvuttra concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran])
      5. Your diagnosis is confirmed by ONE of the following:
         a. Biopsy (removal of cells from the body for examination) of tissue/organ to confirm amyloid (a type of abnormal protein) presence AND chemical typing to confirm presence of TTR (transthyretin) protein
         b. DNA (deoxyribonucleic acid) genetic sequencing (a type of lab test) to confirm hATTR mutation (a type of abnormal gene)

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VUTRISIRAN

INITIAL CRITERIA (CONTINUED)

C. If you have cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis, approval also requires:

1. You are 18 years of age or older
2. Therapy is prescribed by or in consultation with a cardiologist (a type of heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist (doctor who treats gene disorders)
3. You have New York Heart Association (NYHA) Class I, II, or III heart failure (classification of heart failure symptoms)
4. Your diagnosis is confirmed by ONE of the following:
   a. Bone scan (scintigraphy) strongly positive for myocardial uptake of TC-99m-PYP (a type of imaging test) (Note: Strongly positive defined as Grade 2 or 3 uptake using the Perugini Grade 1-3 scoring system)
   b. Biopsy of tissue of the affected organ(s) (removal of cells or tissue from the body for examination) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence AND chemical typing to confirm presence of transthyretin (TTR) protein
5. You will NOT use Amvuttra concurrently (at the same time) with a transthyretin stabilizer (acoramidis [Attruby], tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) for the treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)

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VUTRISIRAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN) (ICD-10 E85.1) and meet **ALL** of the following criteria?
   - The patient has NOT progressed to Familial Amyloid Polyneuropathy (FAP) stage 3 or Polyneuropathy Disability (PND) stage 4 polyneuropathy, as evidenced by functional decline (e.g., wheelchair-bound, bedridden)
   - Amvuttra will NOT be used concurrently with other hATTR-PN agents (e.g., Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.5mL per 3 months.**

   If no, continue to #2.

2. Does the patient have a diagnosis of cardiomyopathy of wild-type transthyretin-mediated amyloidosis (ICD-10 E85.82) or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (ICD-10 E85.4) **AND** meet the following criterion?
   - Amvuttra will NOT be used concurrently with a transthyretin stabilizer (acoramidis [Attruby], tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) for the treatment of ATTR-CM

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #0.5mL per 3 months.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **VUTRISIRAN (Amvuttra)** requires the following rule(s) be met for renewal:

   A. You have ONE of the following:
      1. Hereditary transthyretin-mediated amyloidosis with polyneuropathy (hATTR-PN: a rare genetic disorder with widespread nerve pain/damage)
      2. Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)

   (Renewal denial text continued on next page)

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VUTRISIRAN

RENEWAL CRITERIA (CONTINUED)

B. If you have hereditary transthyretin-mediated amyloidosis with polyneuropathy, renewal also requires:
1. You have NOT progressed to Familial Amyloid Polyneuropathy (FAP: a tool used to evaluate disease severity) stage 3 OR Polyneuropathy Disability (PND: a tool used to evaluate disease severity) stage 4 polyneuropathy, as shown by functional decline (such as being wheelchair-bound, being bedridden)
2. You will NOT use Amvuttra concurrently (at the same time) with other hATTR-PN medications (such as Wainua [eplontersen], Tegsedi [inotersen], Onpattro [patisiran])

C. If you have cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis, renewal also requires:
1. You will NOT use Amvuttra concurrently (at the same time) with a transthyretin stabilizer (acoramidis [Attruby], tafamidis [Vyndamax], tafamidis meglumine [Vyndaqel]) for the treatment of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (heart disease caused by a build-up of a type of protein)

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Amvuttra.

REFERENCES
Amvuttra [Prescribing Information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; March 2025.

Created: 06/22
Effective: 06/10/26 Client Approval: 06/26 DMC Approval: 05/27/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZANIDATAMAB-HRII

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZANIDATAMAB-HRII	ZIIHERA	50014		GPI-10 (2117009001)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of previously treated, unresectable or metastatic biliary tract cancer (BTC) (ICD-10 Group C24) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is human epidermal growth factor receptor 2 (HER2)-positive (IHC 3+), as detected by an FDA-authorized test

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of gastric, gastroesophageal junction, or esophageal adenocarcinoma (GEA) (ICD-10 Groups C15, C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is unresectable locally advanced or metastatic

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer is HER2-positive (IHC 3+ or IHC 2+/ISH+), as detected by an FDA-authorized test, AND Ziihera will be used in combination with fluoropyrimidine- (e.g., fluorouracil, capecitabine) and platinum-containing chemotherapy (e.g., cisplatin, oxaliplatin) and Tevimbra (tislelizumab-jsgr)
   - The patient's cancer is HER2-positive (IHC 3+), as detected by an FDA-authorized test, AND Ziihera will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZANIDATAMAB-HRII

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZANIDATAMAB-HRII (Ziihera)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Biliary tract cancer (BTC: a type of bile duct or gallbladder cancer)
   2. Gastric, gastroesophageal junction, or esophageal adenocarcinoma (GEA: a type of digestive system cancer)

B. If you have biliary tract cancer, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is previously treated, unresectable (unable to remove by surgery) or metastatic (cancer that has spread to other parts of the body)
   3. Your cancer is human epidermal growth factor receptor 2 (HER2)-positive immunohistochemistry 3+ (IHC 3+), as detected by a Food and Drug Administration (FDA)-authorized test

C. If you have gastric, gastroesophageal junction, or esophageal adenocarcinoma, approval also requires:
   1. You are 18 years of age or older
   2. Your cancer is unresectable (cannot be removed by surgery) locally advanced (cancer that has spread from where it started to nearby tissue or lymph nodes) or metastatic (has spread to other parts of the body)
   3. You meet ONE of the following:
      a. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+ or IHC 2+/ISH+), as detected by a Food and Drug Administration (FDA)-authorized test, AND Ziihera will be used in combination with fluoropyrimidine- (such as fluorouracil, capecitabine) and platinum-containing chemotherapy (such as cisplatin, oxaliplatin) and Tevimbra (tislelizumab-jsgr)
      b. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-positive (IHC 3+), as detected by a Food and Drug Administration (FDA)-authorized test, AND Ziihera will be used in combination with fluoropyrimidine- (such as fluorouracil, capecitabine) and platinum-containing chemotherapy (such as cisplatin, oxaliplatin)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ziihera.

REFERENCES

Ziihera [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; August 2026.

Created: 12/24
Effective: 08/29/26 DMC Approval: 09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZANUBRUTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZANUBRUTINIB	BRUKINSA	46212		GPI-10 (2153219500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mantle cell lymphoma (MCL) (ICD-10 Group C83.1) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least ONE prior therapy (e.g., R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
   - The patient had a trial of or contraindication to the preferred agent: Calquence (acalabrutinib) If yes, **approve for 12 months by GPID or GPI-14 for all the of the following:**
     - **80mg: #4 per day.**
     - **160mg: #2 per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of Waldenstrom's macroglobulinemia (WM) (ICD-10 C88.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to the preferred agent: Imbruvica (ibrutinib)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **80mg: #4 per day.**
   - **160mg: #2 per day.**

   If no, continue to #3.

3. Does the patient have a diagnosis of relapsed or refractory marginal zone lymphoma (MZL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has received at least ONE anti-CD20-based regimen (e.g., rituximab)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **80mg: #4 per day.**
   - **160mg: #2 per day.**

   If no, continue to #4.

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ZANUBRUTINIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) (ICD-10 Group C91.1) or small lymphocytic lymphoma (SLL) (ICD-10 Group C83.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Calquence (acalabrutinib), Imbruvica (ibrutinib)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **80mg: #4 per day.**
   - **160mg: #2 per day.**

   If no, continue to #5.

5. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (FL) (ICD-10 Group C82) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Brukinsa will be used in combination with Gazyva (obinutuzumab)
   - Brukinsa will be used after at least TWO lines of systemic therapy (e.g., lenalidomide with rituximab)

   If yes, **approve for 12 months by GPID or GPI-14 for all of the following:**
   - **80mg: #4 per day.**
   - **160mg: #2 per day.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZANUBRUTINIB (Brukinsa)** requires the following rule(s) be met for approval:

   A. You have ONE of the following:
      1. Mantle cell lymphoma (MCL: a type of blood cancer)
      2. Waldenstrom's macroglobulinemia (WM: a type of blood cancer)
      3. Relapsed or refractory marginal zone lymphoma (MZL: a type of blood cancer that has returned or did not respond to treatment)
      4. Chronic lymphocytic leukemia (CLL: a type of blood cancer)
      5. Small lymphocytic lymphoma (SLL: a type of blood cancer)
      6. Relapsed or refractory follicular lymphoma (FL: a type of blood cancer that has returned or did not respond to treatment)

   (Denial text continued on the next page)

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ZANUBRUTINIB

GUIDELINES FOR USE (CONTINUED)

B. If you have mantle cell lymphoma, approval also requires:
1. You are 18 years of age or older
2. You have received at least ONE prior therapy (such as R-CHOP [rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone])
3. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Calquence (acalabrutinib)

C. If you have Waldenstrom's macroglobulinemia, approval also requires:
1. You are 18 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) the preferred medication: Imbruvica (ibrutinib)

D. If you have relapsed or refractory marginal zone lymphoma, approval also requires:
1. You are 18 years of age or older
2. You have received at least ONE anti-CD20-based regimen (a type of blood cancer treatment plan, such as rituximab)

E. If you have chronic lymphocytic leukemia or small lymphocytic lymphoma, approval also requires:
1. You are 18 years of age or older
2. You have tried or have a contraindication to (harmful for you to use) ONE of the following preferred medications: Calquence (acalabrutinib), Imbruvica (ibrutinib)

F. If you have relapsed or refractory follicular lymphoma, approval also requires:
1. You are 18 years of age or older
2. Brukinsa will be used in combination with Gazyva (obinutuzumab)
3. Brukinsa will be used after at least TWO lines of systemic therapy (such as lenalidomide with rituximab)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Brukinsa.

REFERENCES

Brukinsa [Prescribing Information]. San Mateo, CA: BeiGene USA, Inc.; June 2025.

Created: 02/20
Effective: 07/01/26 Client Approval: 06/26 DMC Approval: 06/16/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZAVEGEPANT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZAVEGEPANT HCL	ZAVZPRET	48771		GPI-10 (6770109020)	

GUIDELINES FOR USE

1. Is the request for the acute treatment of migraines (ICD-10 Group G43 except G43.7 and G43.E) and the patient meets **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Zavzpret will NOT be used concurrently with other cGRP inhibitors (e.g., Ubrelvy [ubrogepant]) for the acute treatment of migraines
   - The patient had a trial of or contraindication to the clinical standard of care agent: ONE triptan (e.g., Imitrex [sumatriptan], Maxalt [rizatriptan])
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Reyvow (lasmiditan), Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)
   - The patient is unable to tolerate oral medications

   If yes, **approve for 6 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZAVEGEPANT (Zavzpret)** requires the following rule(s) be met for approval:
   A. The request is for the acute (quick onset) treatment of migraines (a type of headache)
   B. You are 18 years of age or older
   C. You will NOT use Zavzpret concurrently (at the same time) with other calcitonin gene-related peptide (cGRP) inhibitors (such as Ubrelvy [ubrogepant]) for the acute (quick onset) treatment of migraines (a type of headache)
   D. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ONE triptan (such as Imitrex [sumatriptan], Maxalt [rizatriptan])
   E. You have tried or have a contraindication to (harmful for you to use) TWO of the following preferred medications: Reyvow (lasmiditan), Nurtec ODT (rimegepant), Ubrelvy (ubrogepant)
   F. You are NOT able to tolerate oral medications

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zavzpret.

REFERENCES

Zavzpret [Prescribing Information]. New York, NY: Pfizer, Inc.; August 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZERO COPAY OVERRIDE - ASPIRIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ASPIRIN	ASPIRIN, ASPIRIN EC, VARIOUS		161 16713	GPI-14 (64100010000510, 64100010000601)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for a generic medication?

   If yes, **approve for 12 months by GPID or GPI-14 at zero copay.**
   If no, continue to #3.

3. Is the request for a MSB or SSB medication **AND** the patient meets the following criterion?
   - The prescriber has provided medical justification why the generic equivalent cannot be used

   If yes, **approve for 12 months by GPID or GPI-14 at zero copay.**
   APPROVAL TEXT (applies to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ZERO COPAY OVERRIDE - ASPIRIN** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. Your request is for a generic medication
      2. Your request is for a multi-source or single source brand medication (a brand name medication) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZERO COPAY OVERRIDE - ASPIRIN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Aspirin medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of aspirin for preventative use at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on FDA-approved aspirin medications that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed October 2025.

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed October 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZERO COPAY OVERRIDE - BOWEL PREP

Generic	Brand	HICL	GCN	Medi-Span	Exception/ Other
SOD PICOSULF/MAG OX/CITRIC AC	CLENPIQ	24291		GPI-10 (4699200345)	
BISAC/NACL/NAHCO3/KCL/PEG 3350	PEG-PREP	33281		GPI-10 (4699200520)	
PEG3350/SOD SULF,BICARB,CL/KCL	GAVILYTE-C, GAVILYTE-G, GOLYTELY COLYTE WITH FLAVOR PACKS, PEG 3350-ELECTROLYTE, PEG 3350 AND ELECTROLYTES	34667 01344		GPI-10 (4699200530)	
SODIUM CHLORIDE/NAHCO3/ KCL/PEG	NULYTELY, NULYTELY WITH FLAVOR PACKS, GAVILYTE-N, PEG 3350-ELECTROLYTE, TRILYTE WITH FLAVOR PACKETS	07981 33276		GPI-10 (4699200430)	
PEG3350/SOD/SUL/NACL /KCL/ASB/C	MOVIPREP, PLENVU, PEG3350/SOD SUL/NACL/KCL/ASB/C	34026		GPI-10 (4699200630)	
PEG 3350/SOD SULF, CHLR/POT/MAG	SUFLAVE	49038		GPI-10 (4699200538)	
SODIUM, POTASSIUM,MAG SULFATES	SUPREP, SODIUM, POTASSIUM,MAG SULFATES	37152		GPI-10 (4699200360)	
SOD SULF/POT CHLORIDE/MAG SULF	SUTAB	46967		GPI-10 (4699200358)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

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GUIDELINES FOR USE (CONTINUED)

2. Is the patient using the requested medication for colorectal cancer screening **AND** meets the following criterion?
   - The patient is between 45 to 75 years of age

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for a generic or SSB medication?

   If yes, **approve the requested medication for 12 months at zero copay with the following fill counts and quantity limits:**
   FILL COUNT
   - **If no fills in the past 365 days: Approve for 2 fills.**
   - **If 2 or more fills in the past 365 days: Approve for 1 fill.**

   QUANTITY LIMIT
   - **GaviLyte-C, PEG3350/SOD SULF/BICARB/CL/KCL, GaviLyte-N, TriLyte, PEG-PREP: approve by HICL-G or GPI-10-G for #4000mL per fill.**
   - **NuLYTELY: approve by HICL or GPI-10 for #4000mL per fill.**
   - **PEG3350/SOD SUL/NACL/KCL/ASB/C: approve by GPID-G or GPI-14-G for #1 kit per fill.**
   - **SODIUM/POTASSIUM/MAG SULFATES: approve by HICL-G or GPI-10-G for #354mL per fill.**
   - **Plenvu: approve by GPID or GPI-14 for #3 packets per fill.**
   - **Clenpiq: approve by GPID or GPI-14 as follows:**
     - **10mg-3.5g/160mL: #320mL per fill.**
     - **10mg-3.5g/175mL: #350mL per fill.**
   - **Sulfave: approve by HICL or GPI-10 for #2 boxes per fill.**
   - **Sutab: approve by HICL or GPI-10 for #24 tablets per fill.**

   If no, continue to #4.

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ZERO COPAY OVERRIDE - BOWEL PREP

GUIDELINES FOR USE (CONTINUED)

4. Is the request for a MSB medication **AND** the patient meets the following criterion?
   - The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months at zero copay with the following fill counts and quantity limits:**
   FILL COUNT
   - **If no fills in the past 365 days: Approve for 2 fills.**
   - **If 2 or more fills in the past 365 days: Approve for 1 fill.**

   QUANTITY LIMIT
   - **GoLYTELY, CoLyte, GaviLyte-G: approve by HICL or GPI-10 for #4000mL per fill.**
   - **MoviPrep: approve by GPID or GPI-14 for #1 kit per fill.**
   - **Suprep: approve by HICL or GPI-10 for #354mL per fill.**

   APPROVAL TEXT (applicable to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZERO COPAY OVERRIDE - BOWEL PREP** requires the following rule(s) be met for approval:
   A. The requested medication is being used for colorectal cancer screening
   B. You are between 45 to 75 years of age
   C. You meet ONE of the following:
      1. Your request is for a generic medication or single source brand medication (a brand name medication without a generic available)
      2. Your request is for a multi-source medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZERO COPAY OVERRIDE - BOWEL PREP

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for bowel preparation for colonoscopy medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of bowel preparation for colonoscopy medications (used for colorectal cancer screening) at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on FDA-approved bowel preparation for colonoscopy medications that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANASTROZOLE	ARIMIDEX, ANASTROZOLE	10249		GPI-10 (2140281000)	
EXEMESTANE	AROMASIN, EXEMESTANE	20803		GPI-10 (2140283500)	
RALOXIFENE HCL	EVISTA, RALOXIFENE HCL	16917		GPI-10 (3005306010)	
TAMOXIFEN CITRATE	TAMOXIFEN CITRATE		38720 38721	GPI-14 (21402680100310, 21402680100320)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient using the requested medication for prevention (risk reduction) of breast cancer and meets **ALL** of the following criteria?
   - The patient is 35 years of age or older
   - The request is for a dosing quantity of #1 per day

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for a generic medication?

   If yes, **approve the requested medication for 12 months at zero copay with a quantity limit of #1 per day as follows:**
   - **Anastrozole: Approve by HICL-G or GPI-10-G.**
   - **Exemestane: Approve by HICL-G or GPI-10-G.**
   - **Raloxifene: Approve by HICL-G or GPI-10-G.**
   - **Tamoxifen 10mg and 20mg: Approve <u>both</u> by GPID-G or GPI-14-G.**

   If no, continue to #4.

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ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION

GUIDELINES FOR USE (CONTINUED)

4. Is the request for a MSB or SSB medication **AND** the patient meets the following criterion?
   - The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months at zero copay with a quantity limit of #1 per day as follows:**
   - **Arimidex: Approve by HICL or GPI-10.**
   - **Aromasin: Approve by HICL or GPI-10.**
   - **Evista: Approve by HICL or GPI-10.**
   - **Tamoxifen 10mg and 20mg: Approve <u>both</u> by GPID or GPI-14.**

   APPROVAL TEXT (applies to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION** requires the following rule(s) be met for approval:
   A. The requested medication is being used for prevention (risk reduction) of breast cancer
   B. You are 35 years of age or older
   C. You are requesting a quantity of #1 per day
   D. You meet ONE of the following:
      1. Your request is for a generic medication
   E. Your request is for a multi-source or single source brand medication (a brand name medication with or without a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZERO COPAY OVERRIDE - BREAST CANCER PREVENTION

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for breast cancer prevention medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of medications for breast cancer prevention at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on FDA-approved medications for breast cancer prevention that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZERO COPAY OVERRIDE - CONTRACEPTIVE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CONTRACEPTIVES, ORAL				GPI-2 (25)	STC = 0248
CONTRACEPTIVES, TRANSDERMAL					STC = 9495
CONTRACEPTIVES, INTRAVAGINAL, SYSTEMIC					STC = 9654
INTRA-UTERINE DEVICES (IUD'S)					STC = 4730
CONTRACEPTIVES, INJECTABLE					STC = 4139
CONTRACEPTIVES, IMPLANTABLE					STC = 3669
CONTRACEPTIVE, INTRAVAGINAL				GPI-10 (5530001000)	STC = 0249
DIAPHRAGMS/CERVICAL CAP				GPI-10 (9740208000) (9740181000) (9740201000)	STC = 3322
CONDOMS, VARIED				GPI-2 (97)	STC = 4650

GUIDELINES FOR USE

1. Does the plan cover the requested contraceptive at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit [EHB] Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for an ORAL contraceptive?

   If yes, continue to #3.
   If no, continue to #7.

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ZERO COPAY OVERRIDE - CONTRACEPTIVE

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following criteria?
   - The request is for a quantity of #1 per day
   - The request is for a quantity greater than #1 per day AND the prescriber has provided medical justification as to why the requested quantity is needed for contraception (e.g., continuous therapy, skipping placebo pills, etc.)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for a generic medication?

   If yes, **approve the requested medication and quantity for 12 months by HICL-G or GPI-10-G at zero copay.**

   If no, continue to #5.

5. Is the request for a SSB medication?

   If yes, **approve the requested medication and quantity for 12 months by HICL or GPI-10 at zero copay.**

   If no, continue to #6.

6. Is the request for a MSB medication **AND** the patient meets the following criterion?
   - The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication and quantity for 12 months by HICL or GPI-10 at zero copay.**
   APPROVAL TEXT (applies to multi-source brand medications only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZERO COPAY OVERRIDE - CONTRACEPTIVE

GUIDELINES FOR USE (CONTINUED)

7. Is the request for a condom?

   If yes, continue to #8.
   If no, continue to #9.

8. Does the patient meet **ONE** of the following criteria?
   - The request is for a quantity of #60 per fill
   - The request is for a quantity greater than #60 per fill AND the prescriber has provided medical justification as to why the requested quantity is needed for contraception

   If yes, **approve the requested quantity for 12 months by HICL or GPI-10 at zero copay.**
   If no, do not approve**.**
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Is the request for a generic medication?

   If yes, **approve the requested medication for 12 months by HICL-G or GPI-10-G at zero copay.**

   If no, continue to #10.

10. Is the request for a SSB medication?

    If yes, **approve the requested medication for 12 months by HICL or GPI-10 at zero copay.**
    If no, continue to #11.

11. Is the request for a MSB medication **AND** the patient meets the following criterion?
    - The prescriber has provided medical justification as to why the generic equivalent cannot be used

    If yes, **approve the requested medication for 12 months by HICL or GPI-10 at zero copay.**
    APPROVAL TEXT (applies to multi-source brand medications only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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ZERO COPAY OVERRIDE - CONTRACEPTIVE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZERO COPAY OVERRIDE - CONTRACEPTIVE** requires that the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. Your request is for a generic or a single source brand medication (a brand name medication without a generic available)
   2. Your request is for a multi-source brand medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

B. If your request is for an oral contraceptive, approval also requires ONE of the following:
   1. Your request is for a quantity of #1 per day
   2. Your request is for a quantity greater than #1 per day AND your doctor has provided medical justification as to why the requested quantity is needed for contraception (such as continuous therapy, skipping placebo pills)

C. If your request is for a condom, approval also requires ONE of the following:
   1. Your request is for a quantity of #60 per prescription fill
   2. Your request is for a quantity greater than #60 per fill AND your doctor has provided medical justification as to why the requested quantity is needed for contraception

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for contraceptive medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of contraceptives at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on FDA-approved contraceptive methods that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZERO COPAY OVERRIDE - FLUORIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FLUORIDE (SODIUM)	FLURA-DROPS, SOLUVITA, FLUORIDE, SODIUM FLUORIDE, LUDENT FLUORIDE		7472 7473 7510 7511 7512	GPI-14 (79300020000505, 79300020000510, 79300020000515, 79300020002050)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient 6 months to 6 years of age?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for a generic medication?

   If yes, **approve the requested medication for 12 months by GPID-G or GPI-14-G at zero copay.**

   If no, continue to #4.

4. Is the request for a MSB or SSB medication **AND** the patient meets the following criterion?
   - The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 at zero copay.**
   APPROVAL TEXT (applies to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZERO COPAY OVERRIDE - FLUORIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZERO COPAY OVERRIDE - FLUORIDE** requires the following rule(s) be met for approval:

A. You are 6 months to 6 years of age
B. You meet ONE of the following:
    1. Your request is for a generic medication
    2. Your request is for a multi-source or single source brand medication (a brand name medication with or without a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for fluoride medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of fluoride at zero copay. The override criteria allow patients access a zero copay by waiving the applicable cost-sharing on FDA-approved fluoride medications that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZERO COPAY OVERRIDE - FOLIC ACID

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOLIC ACID	FOLIC ACID		94783 94784	GPI-14 (82200010000305, 82200010000310)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the request for a generic medication?

   If yes, **approve the requested medication for 12 months by GPID-G or GPI-14-G at zero copay.**

   If no, continue to #3.

3. Is the request for a MSB or SSB medication **AND** the patient meets the following criterion?
   - The prescriber has provided medical justification why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 at zero copay. APPROVAL TEXT (applies to multi-source brand agents only):** Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ZERO COPAY OVERRIDE - FOLIC ACID** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. Your request is for a generic medication
      2. Your request is for a multi-source or single source brand medication (a brand name medication with or without a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication.

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZERO COPAY OVERRIDE - FOLIC ACID

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for folic acid medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of folic acid 0.4mg and 0.8mg tablets at zero copay. The override criteria allow patient a zero copay by waiving the applicable cost-sharing on FDA-approved folic acid medications that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	TRUVADA, EMTRICITABINE/ TENOFOVIR DISOPROXIL FUMARATE		23152	GPI-14 (12109902300320)	
EMTRICITABINE/TENOFOVIR ALAFENAMIDE FUMARATE	DESCOVY		40953	GPI-14 (12109902290320)	
TENOFOVIR DISOPROXIL FUMARATE	VIREAD, TENOFOVIR DISOPROXIL FUMARATE		14822	GPI-14 (12108570100320)	
EMTRICITABINE	EMTRIVA, EMTRICITABINE		20019	GPI-14 (12106030000120)	
CABOTEGRAVIR	APRETUDE	47270		GPI-10 (1210301000)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Does the patient meet **ALL** of the following criteria?
   - The requested medication is FDA-approved for PrEP or recommended by the CDC PrEP Guidelines
   - The requested medication will NOT be used concurrently with another HIV medication for the treatment of HIV
   - The request is for a dosing quantity of #1 per day for Truvada (emtricitabine/tenofovir disoproxil fumarate), Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine), and Descovy (emtricitabine and tenofovir alafenamide)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS

GUIDELINES FOR USE (CONTINUED)

3. Is the request for a generic or SSB medication?

   If yes, **approve the requested medication for 12 months as follows:**
   - **Emtricitabine/tenofovir: Approve by GPID-G or GPI-14-G with a quantity limit of #1 per day. at zero copay.**
   - **Descovy: Approve by GPID or GPI-14 with a quantity limit of #1 per day.**
   - **Tenofovir disoproxil: Approve by GPID-G or GPI-14-G with a quantity limit of #1 per day.**
   - **Emtricitabine: Approve by GPID-G or GPI-14-G with a quantity limit of #1 per day.**
   - **Apretude : Approve by HICL or GPI-10 for 7 fills.**

   If no, continue to #4.

4. Is the request for a MSB medication **AND** the patient meets the following criterion?
   - The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months at zero copay as follows:**
   - **Truvada: Approve by GPID or GPI-14 with a quantity limit of #1 per day.**
   - **Viread: Approve by GPID or GPI-14 with a quantity limit of #1 per day.**
   - **Emtriva: Approve by GPID or GPI-14 with a quantity limit of #1 per day.**

   APPROVAL TEXT (applies to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ZERO COPAY OVERRIDE - PRE-EXPOSURE PROPHYLAXIS** requires the following rule(s) be met for approval:

A. The requested medication is FDA (Food and Drug Administration)-approved for pre-exposure prophylaxis (PrEP) OR recommended by the CDC (Centers for Disease Control and Prevention) PrEP Guidelines
B. The requested medication will NOT be used concurrently (at the same time) with another human immunodeficiency virus (HIV) medication for the treatment of HIV
C. Your request is for a dosing quantity of #1 per day for Truvada (emtricitabine/tenofovir disoproxil fumarate), Viread (tenofovir disoproxil fumarate), Emtriva (emtricitabine), and Descovy (emtricitabine and tenofovir alafenamide)
D. You meet ONE of the following:
    1. Your request is for a generic or a single source brand medication (a brand name medication without a generic available)
    2. Your request is for a multi-source brand medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pre-Exposure Prophylaxis (PrEP) medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of medications for Pre-Exposure Prophylaxis (PrEP) at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on FDA-approved medications for breast cancer prevention that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: : https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource- center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZERO COPAY OVERRIDE - SMOKING CESSATION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUPROPION HCL	ZYBAN, BUROPION HCL SR		27901	GPI-10 (6210000210)	
VARENICLINE TARTRATE	CHANTIX, VARENICLINE TARTRATE		27046 27047 27048	GPI-10 (6210008020)	
NICOTINE	NICOTROL, NICOTROL NS, NICOTINE PATCH, NICODERM CQ, NICOTINE	06249		GPI-10 (6210000500)	
NICOTINE POLACRILEX	NICOTINE GUM, NICOTINE LOZENGE, NICORETTE, VARIOUS	02049		GPI-14 (6210001000)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

2. Is the patient 18 years of age or older?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the request for a generic medication?

   If yes, **approve the requested medication/agent for 12 months by GPID-G or GPI-14-G at zero copay.**

   If no, continue to #4.

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ZERO COPAY OVERRIDE - SMOKING CESSATION

GUIDELINES FOR USE (CONTINUED)

4. Is the request for a MSB medication **AND** the patient meets the following criterion?
   - The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested agent for 12 months by GPID or GPI-14 at zero copay. APPROVAL TEXT (applicable to multi-source brand agents only):** Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ZERO COPAY OVERRIDE - SMOKING CESSATION** requires the following rule(s) be met for approval:
   A. You are 18 years of age or older
   B. You meet ONE of the following:
      1. Your request is for a generic
      2. Your request is for a multi-source medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZERO COPAY OVERRIDE - SMOKING CESSATION

RATIONALE

This guideline applies to plans where the pharmacy benefit allows for coverage of smoking cessation medication at zero copay. The override criteria allow patient access to all FDA-approved smoking cessation medications at zero copay.

This guideline applies to plans where the pharmacy benefit allows for coverage of medications for smoking cessation at zero copay. The override criteria allow patients a zero copay by waiving the applicable cost-sharing on smoking cessation agents that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: : https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource- center/faqs/aca-part-xxvi.pdf. Accessed September 2024

The Center for Consumer Information & Insurance Oversight: Affordable Care Act Implementation FAQs – Set 18: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18. Accessed September 2024

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZERO COPAY OVERRIDE - STATIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROSUVASTATIN CALCIUM	CRESTOR, ROSUVASTATIN CALCIUM		19153 20229	GPI-14 (39400060100305, 39400060100310)	
PRAVASTATIN SODIUM	PRAVACHOL, PRAVASTATIN SODIUM	06227		GPI-10 (3940006510)	
SIMVASTATIN	ZOCOR, SIMVASTATIN		26531 26532 26533 26534	GPI-14 (39400075000310, 39400075000320, 39400075000330, 39400075000340)	
ATORVASTATIN CALCIUM	LIPITOR, ATORVASTATIN CALCIUM		43720 43721	GPI-14 (39400010100310, 39400010100320)	
LOVASTATIN, LOVASTATIN EXTENDED-RELEASE	ALTOPREV, LOVASTATIN	02793		GPI-10 (3940005000)	
FLUVASTATIN SODIUM , FLUVASTATIN EXTENDED-RELEASE	LESCOL, FLUVASTATIN SODIUM, LESCOL XL, FLUVASTATIN EXTENDED-RELEASE	08946		GPI-10 (3940003010)	
PITAVASTATIN CALCIUM	LIVALO, PITAVASTATIN CALCIUM	36983		GPI-10 (3940005810)	
PITAVASTATIN MAGNESIUM	ZYPITAMAG, PITAVASTATIN MAGNESIUM	44422		GPI-10 (3940005830)	

GUIDELINES FOR USE

1. Does the plan cover the requested medication at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

   If yes, continue to #2.
   If no, guideline does not apply.

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ZERO COPAY OVERRIDE - STATIN

GUIDELINES FOR USE (CONTINUED)

2. Does the patient meet **ALL** of the following criteria?
   - The patient is between 40 to 75 years old
   - The patient is not concurrently taking any of the below secondary prevention medications for cardiovascular disease:
     - Aspirin/dipyridamole (Aggrenox)
     - Clopidogrel (Plavix)
     - Dipyridamole
     - Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
     - Prasugrel (Effient)
     - Ticagrelor (Brilinta)
     - Ticlopidine
     - Vorapaxar (Zontivity)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the requested quantity within the low to moderate intensity daily dosage as shown below?
   - Atorvastatin (Lipitor): 10 - 20 mg
   - Fluvastatin (Lescol): 20 - 80 mg (40 mg twice daily)
   - Fluvastatin ER (Lescol XL): 80 mg
   - Lovastatin: 10 - 40 mg
   - Pitavastatin calcium (Livalo): 1 - 4 mg
   - Pravastatin (Pravachol): 10 - 80 mg
   - Rosuvastatin (Crestor): 5 - 10 mg
   - Simvastatin (Zocor): 5 - 40 mg

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for a generic medication?

   If yes, **approve the requested medication for 12 months by GPID-G or GPI-14-G at zero copay.**

   If no, continue to #5.

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ZERO COPAY OVERRIDE - STATIN

GUIDELINES FOR USE (CONTINUED)

5. Is the request for a MSB medication **AND** the patient meets the following criterion?
   - The prescriber has provided medical justification as to why the generic equivalent cannot be used

   If yes, **approve the requested medication for 12 months by GPID or GPI-14 at zero copay. APPROVAL TEXT (applicable to multi-source brand agents only):** Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

   If no, do not approve.

   DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **ZERO COPAY OVERRIDE - STATIN** requires the following rule(s) be met for approval:

   A. You are between 40 to 75 years old
   B. You are not concurrently (at the same time) taking any of the below secondary prevention medications for cardiovascular disease (heart disease):
      1. Aspirin/dipyridamole (Aggrenox)
      2. Clopidogrel (Plavix)
      3. Dipyridamole
      4. Nitroglycerin (oral, sublingual, transdermal, translingual dosage forms)
      5. Prasugrel (Effient)
      6. Ticagrelor (Brilinta)
      7. Ticlopidine
      8. Vorapaxar (Zontivity)
   C. The requested quantity is within the low to moderate intensity daily dosage as shown below:
      1. Atorvastatin (Lipitor): 10 - 20 mg
      2. Fluvastatin (Lescol): 20 - 80 mg (40 mg twice daily)
      3. Fluvastatin ER (Lescol XL): 80 mg
      4. Lovastatin: 10 - 40 mg
      5. Pitavastatin calcium (Livalo): 1 - 4 mg
      6. Pravastatin (Pravachol): 10 - 80 mg
      7. Rosuvastatin (Crestor): 5 - 10 mg

   (Denial text continued on next page)

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ZERO COPAY OVERRIDE - STATIN

GUIDELINES FOR USE (CONTINUED)

D. You meet ONE of the following:
   1. Your request is for a generic medication
   2. Your request is for a multi-source brand medication (a brand name medication with a generic available) and your doctor provided a medical reason why you cannot use the generic equivalent of the requested medication

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for statin medications listed.

This guideline applies to plans where the pharmacy benefit allows for coverage of low-to-moderate intensity statins at zero copay. The override criteria allow patient a zero copay by waiving the applicable cost-sharing to all FDA-approved low-to-moderate intensity statins that are included in the MedImpact EHB Zero Dollar Copay List.

REFERENCES

U.S. Preventive Services Task Force [Final Summary]. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication. Updated August 2022. Available at: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/statin-use-in-adults-preventive-medication. Accessed October 2025.

U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs. Accessed October 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZIFTOMENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZIFTOMENIB	KOMZIFTI	51002		GPI-10 (2148009000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) (ICD-10 C92.02, C92.00) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a susceptible nucleophosmin 1 (NPM1) mutation
   - The patient has no satisfactory alternative treatment options

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZIFTOMENIB (Komzifti)** requires the following rule(s) be met for approval:
   A. You have relapsed or refractory acute myeloid leukemia (AML) (a type of blood cancer that has returned or did not respond to treatment)
   B. You are 18 years of age or older
   C. You have a susceptible nucleophosmin 1 (NPM1) mutation (an abnormal change in a type of gene)
   D. You have no satisfactory alternative treatment options

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Komzifti.

REFERENCES

Komzifti [Prescribing Information]. San Diego, CA: Kura Oncology, Inc.; November 2025.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZILUCOPLAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZILUCOPLAN SODIUM	ZILBRYSQ	49273		GPI-10 (8580509520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a neurologist
   - The patient has a positive serologic test for anti-acetylcholine receptor antibody (AChR-Ab+)
   - The patient is Myasthenia Gravis Foundation of America class II, III, or IV
   - The patient had a trial of or contraindication to ONE corticosteroid (e.g., prednisone)
   - The patient had a trial of or contraindication to ONE of the following preferred agents: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod- hyaluronidase-qvfc)
   - Zilbrysq will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]), or CD-19 antibody (e.g., Uplizna [inebilizumab- cdon]) for the treatment of gMG

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of or contraindication to TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
   - The patient had a trial of or contraindication to ONE non-steroidal immunosuppressive therapy if on chronic plasmapheresis or plasma exchange

   If yes, **approve the requested strength for 6 months by GPID or GPI-14 with the following quantity limits:**
   - **16.6mg syringe: #0.416mL per day.**
   - **23mg syringe: #0.574mL per day.**
   - **32.4mg syringe: #0.81mL per day.**

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ZILUCOPLAN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ZILUCOPLAN (Zilbrysq)** requires the following rule(s) be met for approval:

A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or in consultation with a neurologist (a type of brain and nervous system doctor)
D. You have a positive serologic test for the anti-acetylcholine receptor antibody (AChR-Ab+: a type of blood test that shows you have myasthenia gravis)
E. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
F. You have tried or have a contraindication to (harmful for you to use) ONE corticosteroid (such as prednisone)
G. You have tried or have a contraindication to ONE of the following preferred medications: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab)/Vyvgart Hytrulo (efgartigimod-hyaluronidase-qvfc)
H. You will NOT use Zilbrysq concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis
I. You meet ONE of the following:
    1. You have tried or have a contraindication to (harmful for you to use) TWO non-steroidal immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
    2. You have tried or have a contraindication to ONE non-steroidal immunosuppressive therapy if you are on chronic plasmapheresis or plasma exchange (types of blood therapy)

This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZILUCOPLAN

RENEWAL CRITERIA

1. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) (ICD-10 Group G70.0) and meet **ALL** of the following criteria?
   - The patient has had clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   - Zilbrysq will NOT be used concurrently with another neonatal Fc receptor blocker (e.g., Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (e.g., Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]), or CD-19 antibody (e.g., Uplizna [inebilizumab- cdon]) for the treatment of gMG

   If yes, **approve the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**
   - **16.6mg syringe: #0.416mL per day.**
   - **23mg syringe: #0.574mL per day.**
   - **32.4mg syringe: #0.81mL per day.**

   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZILUCOPLAN (Zilbrysq)** requires the following rule(s) be met for renewal:
   A. You have generalized myasthenia gravis (gMG: a chronic autoimmune disorder)
   B. You have had clinical benefit compared to baseline (before treatment) according to validated gMG instruments (such as the Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
   C. You will NOT use Zilbrysq concurrently (at the same time) with another neonatal Fc receptor blocker (such as Rystiggo [rozanolixizumab-noli], Vyvgart [efgartigimod alfa-fcab]), complement inhibitor (such as Soliris [eculizumab], Ultomiris [ravulizumab-cwvz]), or CD-19 antibody (such as Uplizna [inebilizumab-cdon]) for the treatment of generalized myasthenia gravis

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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ZILUCOPLAN

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zilbrysq.

REFERENCES

Zilbrysq [Prescribing Information]. Smyrna, GA: UCB, Inc.; February 2025.

Created: 01/24
Effective: 02/01/26 Client Approval: 01/26 P&T Approval: 04/25

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZIV-AFLIBERCEPT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZIV-AFLIBERCEPT	ZALTRAP		32988 32989	GPI-10 (2133501010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) (ICD-10 C19) and meet ALL of the following criteria?
   - The patient's cancer is resistant to or has progressed following an oxaliplatin-containing regimen (e.g., FOLFOX [leucovorin, fluorouracil, oxaliplatin])
   - Zaltrap will be used in combination with fluorouracil, leucovorin, irinotecan (FOLFIRI)

   If yes, **approve for 12 months by GPID or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZIV-AFLIBERCEPT** requires the following rule(s) be met for approval:
   A. You have metastatic colorectal cancer (a type of digestive tract cancer that has spread to other parts of the body)
   B. Your cancer is resistant to (no longer responds) or has progressed (worsened) following an oxaliplatin-containing regimen (a type of cancer treatment such as FOLFOX [leucovorin, fluorouracil, oxaliplatin])
   C. You will use Zaltrap in combination with fluorouracil, leucovorin, irinotecan (FOLFIRI: a type of cancer treatment)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zaltrap.

REFERENCES

Zaltrap [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC. May 2025.

Created: 02/13
Effective: 02/09/26 Client Approval: 01/26 P&T Approval: 11/13

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZOLBETUXIMAB-CLZB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZOLBETUXIMAB-CLZB	VYLOY	49949		GPI-10 (2135519005)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (ICD-10 Group C16) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's cancer is human epidermal growth factor receptor 2 (HER2)-negative
   - The patient's tumors are claudin (CLDN) 18.2 positive, as determined by an FDA-approved test
   - Vyloy will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy (e.g., mFOLFOX6 [fluorouracil, leucovorin, oxaliplatin], CAPOX [capecitabine, oxaliplatin])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZOLBETUXIMAB-CLZB (Vyloy)** requires the following rule(s) be met for approval:
   A. You have locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma (a type of digestive system cancer that cannot be surgically removed, has spread to nearby tissue, or has spread to other parts of the body)
   B. You are 18 years of age or older
   C. Your cancer is human epidermal growth factor receptor 2 (HER2: a type of protein)-negative
   D. Your tumors are claudin (CLDN) 18.2 (a type of protein) positive, as determined by a Food and Drug Administration (FDA)-approved test
   E. Vyloy will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy (a type of cancer treatment such as mFOLFOX6 [fluorouracil, leucovorin, oxaliplatin], CAPOX [capecitabine, oxaliplatin])

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyloy.

REFERENCES

Vyloy [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; June 2025.

Created: 10/24
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZOLIFLODACIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZOLIFLODACIN	NUZOLVENCE	51065		GPI-10 (1600009500)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of uncomplicated urogenital gonorrhea (ICD-10 Group A54.0) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient's infection is caused by *Neisseria gonorrhoeae*
   - The patient had a trial of or contraindication to the clinical standard of care agent: ceftriaxone

   If yes, **approve for 1 month by HICL or GPI-10 for 1 fill.**
   If no, do not approve.

   DENIAL TEXT: Our guideline named **ZOLIFLODACIN (Nuzolvence)** requires the following rule(s) be met for approval:
   A. You have uncomplicated urogenital gonorrhea (a type of bacterial infection)
   B. You are 12 years of age or older
   C. Your infection is caused by Neisseria gonorrhoeae (a type of bacteria)
   D. You have tried or have a contraindication to (harmful for you to use) the clinical standard of care medication: ceftriaxone

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuzolvence.

REFERENCES

Nuzolvence [Prescribing Information]. Waltham, MA: Entasis Therapeutics, Inc.; December 2025.

Created: 09/26
Effective: 09/12/26 Client Approval: 09/26 DMC Approval: 09/09/26

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZONGERTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZONGERTINIB	HERNEXEOS	50811		GPI-10 (2117009200)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) (ICD-10 Group C34) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZONGERTINIB (Hernexeos)** requires the following rule(s) be met for approval:
   A. You have unresectable (unable to remove by surgery) or metastatic (cancer that has spread to other parts of the body) non-squamous non-small cell lung cancer (NSCLC: a type of lung cancer)
   B. You are 18 years of age or older
   C. Your tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations (abnormal change in a type of gene), as detected by a Food and Drug Administration (FDA)-approved test

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hernexeos.

REFERENCES

Hernexeos[Prescribing Information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; February 2026.

Created: 08/25
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZONISAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZONISAMIDE	ZONISADE	21140		GPI-10 (7260009000)	BRAND = ZONISADE

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Groups G40.1, G40.2) and meet **ALL** of the following criteria?
   - The patient is 16 years of age or older
   - Zonisade will be used as adjunctive treatment
   - The patient has a contraindication to or is unable to swallow zonisamide capsules
   - The patient had a trial of or contraindication to THREE antiepileptic medications (e.g., carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam IR or ER, gabapentin, zonisamide capsules, topiramate, lamotrigine)

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30 mL per day.** If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZONISAMIDE (Zonisade)** requires the following rule(s) be met for approval:
   A. You have partial-onset seizures (a type of seizure)
   B. You are 16 years of age or older
   C. Zonisade will be used as adjunctive (add-on) treatment
   D. You have a contraindication to (harmful for you to use) or are unable to swallow zonisamide capsules
   E. You have tried or have a contraindication to (harmful for you to use) THREE antiepileptic medications (medications used to treat seizures, such as carbamazepine, divalproex, valproic acid, oxcarbazepine, levetiracetam immediate-release or extended-release, gabapentin, zonisamide capsules, topiramate, lamotrigine)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZONISAMIDE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of partial-onset seizures (ICD-10 Groups G40.1, G40.2)?

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #30 mL per day.**
   If no, do not approve.

   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZONISAMIDE (Zonisade)** requires the following rule(s) be met for renewal:
   A. You have partial-onset seizures (a type of seizure)

   This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zonisade.

REFERENCES

Zonisade [Prescribing Information]. Wilmington, MA: Azurity Pharmaceuticals, Inc.; March 2023.

Created: 11/22
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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ZURANOLONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ZURANOLONE	ZURZUVAE	49127		GPI-10 (5806009000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postpartum depression (PPD) (ICD-10 F53.0)?

   If yes, **approve for 30 days by GPID or GPI-14 for the requested strength with the following quantity limits:**
   - **20mg: #28 per 14 days for 1 fill.**
   - **25mg: #28 per 14 days for 1 fill.**
   - **30mg: #14 per 14 days for 1 fill.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **ZURANOLONE (Zurzuvae)** requires the following rule(s) be met for approval:
   A. You have postpartum depression (PPD: a type of depression that occurs after giving birth)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zurzuvae.

REFERENCES

Zurzuvae [Prescribing Information]. Cambridge, MA: Biogen Inc.; July 2024.

Library	Commercial	NSA
Yes	Yes	No

Created: 11/23
Effective: 01/01/25 Client Approval: 11/24 P&T Approval: 07/23

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