Acitretin
Prior Authorization Guidelines

**Affected Medication(s)**
- Acitretin oral capsule

**FDA Approved Indication(s)**
- For treatment of severe psoriasis in adults

**Dosing**
- 25 to 50 mg once daily

**Initial Authorization Criteria**

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is acitretin being requested for psoriasis? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, continue to #9

4. Does the member currently have severe inflammatory skin disease defined as having functional impairment (e.g. inability to use hands or feet or activities of daily living, or significant facial involvement preventing normal social interaction AND one or more of the following: At least 10% of body surface area involved AND/OR Hand, foot or mucous membrane involvement? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, continue to #6
5. Have the required labs/diagnostic results been completed and are current?
   a. If yes, continue to #6
   b. If no, deny for needing updated labs/testing

6. Does the member have a contraindication or clinical rationale for avoiding moderate to high potency corticosteroids? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is documentation of a trial with insufficient response provided for at least ONE of the following? (provide supporting documentation)
   - Phototherapy OR
   - Minimum 12-week trial of methotrexate
   a. If yes, approve for 6 months
   b. If no, continue to #8

8. Does the member have a contraindication or history of intolerance to phototherapy OR methotrexate? (Document contraindication and/or intolerance. Note: 1. Alcohol consumption is not considered a contraindication to methotrexate. 2. Nausea to oral formulation is not considered as intolerance to methotrexate) (Provide supporting documentation)
   a. If yes, approve for 6 months
   b. If no, clinical review required

9. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options for the requested indication? (Provide supporting documentation)
   a. If yes, continue to #10
   b. If no, clinical review required

10. Is the requested treatment dose appropriate? (Provide supporting documentation)
    a. If yes, continue to #11
    b. If no, clinical review required
11. Is the treatment being prescribed by or in consultation with an appropriate specialist?

   a. If yes, approve for 3 months
   b. If no, clinical review required

Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

# Aranesp (darbepoetin alfa) Prior Authorization Guidelines

## Affected Medication(s)

- Aranesp subcutaneous injection solution

## FDA Approved Indication(s)

- Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis
- Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy

## Dosing

- Refer to package insert for specific dosing recommendations

## Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, deny. Not funded by OHP

2. Is the request for use to treat an FDA approved or major compendia supported indication?
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. Is the request a renewal of a previously approved Aranesp (darbepoetin alfa) prior authorization and the indication is for the same as previous approval?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #4

4. Have serum ferritin, transferrin saturation, hematocrit (Hct), and hemoglobin (Hb) lab values been completed within 30 days of planned administration? (Provide supporting documentation)
5. Does the member have a serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the member's hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Have other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) been ruled out? (Provide supporting documentation)
   a. If yes, continue to #8
   b. If no, clinical review required

8. Which indication is Aranesp (darbepoetin alfa) being requested for?
   a. Anemia secondary to myelodysplastic syndrome (MDS), continue to corresponding criteria
   b. Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis, continue to corresponding criteria
   c. Anemia secondary to chemotherapy treatment, continue to corresponding criteria
   d. Anemia secondary to chronic kidney disease (non-dialysis patients), approve for 45 days
   e. Other indication, continue to corresponding criteria

Anemia secondary to myelodysplastic syndrome (MDS)

1. Does the member have symptomatic anemia? (Examples include: exertional dyspnea, dyspnea at rest, fatigue, lethargy, confusion, etc.) (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member's endogenous serum erythropoietin level ≤ 500 mUnits/mL? (Provide supporting documentation)
Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis

1. Is the member's endogenous serum erythropoietin level < 500 mUnits/mL? (Provide supporting documentation)
   a. If yes, approve for 45 days unless otherwise specified
   b. If no, clinical review required

Anemia secondary to chemotherapy treatment

1. Is the member receiving concurrent myelosuppressive chemotherapy for non-myeloid malignancies? (examples include platinum-containing chemotherapy, etoposide, anthracyclines, ifosfamide, cyclophosphamide) (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the therapy intention of the chemotherapy curative?
   a. If yes, clinical review required
   b. If no, continue to #3

3. Are there two or more additional months of planned chemotherapy remaining? (Provide supporting documentation)
   a. If yes, approve for 45 days unless otherwise specified
   b. If no, clinical review required

Other Indications

1. Is the requested use supported by major compendia?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member tried and had an inadequate response OR dose the member have a contradiction to ALL standard treatment options for the requested indication? (Provide supporting documentation)
### Reauthorization Criteria

1. Was the last dose of Aranesp (darbepoetin alfa) less than 60 days ago?
   - a. If yes, continue to #2
   - b. If no, clinical review required

2. Were updated chart notes (within 1 year) provided with documentation of significant clinical response to therapy? (Response to therapy includes stabilized hemoglobin and a decreased need for blood transfusions compared to pre-treatment) (Provide supporting documentation)
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. Is there documentation of an absence of unacceptable toxicity from the drug? (Examples include pure red cell aplasia, severe allergic reactions (anaphylaxis, angioedema, bronchospasm, etc), severe cardiovascular events (stroke, myocardial infarction, congestive heart failure, thromboembolism, uncontrolled hypertension), seizures, increased risk of tumor progression/recurrence in members with cancer, etc) (Provide supporting documentation)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. Were lab values obtained within 30 days of the date of administration (unless otherwise indicated)? (hemoglobin and hematocrit) (Provide supporting documentation)
   - a. If yes, continue to #5
   - b. If no, clinical review required

5. Does the member have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months? (Provide supporting documentation)
   - a. If yes, continue to #6
   - b. If no, clinical review required

6. Have other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) been ruled out? (Provide supporting documentation)
   - a. If yes, continue to #7
   - b. If no, clinical review required
7. Does the member meet the diagnosis and clinical requirements for at least one of the following below? (Provide supporting documentation)

- Anemia secondary to myelodysplastic syndrome (MDS) with hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) <36%
- Anemia secondary to myeloproliferative neoplasms (MF, post-PV myelofibrosis, post-ET myelofibrosis) with hemoglobin (Hb) <10 g/dL and/or Hematocrit (Hct) <30%
- Anemia secondary to palliative myelosupressive chemotherapy for non-myeloid malignancies with hemoglobin (Hb) <10 g/dL and/or hematocrit (Hct) <30% and requesting Aranesp to be used concurrently with chemotherapy with minimum two additional months of therapy remaining
- Anemia secondary to chronic kidney disease with hemoglobin (Hb) <12 g/dL and/or hematocrit (Hct) <36% in pediatric patients OR hemoglobin (Hb) <11 g/dL and/or hematocrit (Hct) <33% in adult patients
- Use supported by major compendia
  
a. If yes, approve for 45 days unless otherwise specified
b. If no, clinical review required

**Note:**

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**References:**

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) darbepoetin alfa. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.”

To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Cancer-and Chemotherapy-Induced Anemia Version 1.2018. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the...
National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.


Banzel® (rufinamide)
Prior Authorization Guidelines

**Affected Medication(s)**

- Banzel oral tablet
- Banzel oral suspension

**FDA Approved Indication(s)**

- Adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in adults and pediatric patients 1 year of age and older

**Dosing**

- Maximum dose of 45 mg/kg per day, not to exceed 3200 mg per day

**Initial Authorization Criteria**

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, deny. Not funded by OHP

2. Is the request for renewal of a previously approved Banzel (rufinamide) prior authorization with the same indication?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #3

3. Is Banzel (rufinamide) being requested for an FDA approved indication? (Provide supporting documentation)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. Has the member previously tried ONE of the following therapies - valproate, lamotrigine? (Provide supporting documentation)
   - a. If yes, continue to #6
   - b. If no, continue to #5
5. Did the member have history of intolerance or a contraindication to valproate or lamotrigine? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the member have familial short QT syndrome? (Provide supporting documentation)
   a. If yes, clinical review required
   b. If no, continue to #7

7. Is the treatment being prescribed by or in consultation with a neurologist?
   a. If yes, approve for 12 months
   b. If no, clinical review required

### Reauthorization Criteria

1. Is Banzel (rufinamide) being requested for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the treatment being prescribed by or in consultation with a neurologist?
   a. If yes, approve for 12 months reauthorization
   b. If no, clinical review required

**Note:**

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

**References:**


Benznidazole
Prior Authorization Guidelines

Affected Medication(s)

- Benznidazole oral tablet

FDA Approved Indication(s)

- Treatment of Chagas Disease (American trypanosomiasis), caused by *Trypanosoma cruzi* in pediatric patients 2 to 12 years of age

Dosing

- Weight based dosing with maximum of 200 mg twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request for renewal of a previously approved Benznidazole prior authorization with the same indication?
   a. If yes, clinical review required
   b. If no, continue to #3

3. Is Benznidazole being requested for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is a lab result confirming *T. cruzi* infection provided? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the requested treatment being prescribed by or in consultation with an infectious disease specialist or a cardiologist?
   a. If yes, approve for 60 days
b. If no, clinical review required

Note:
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References:


### Affected Medication(s)

- Calcipotriene 0.005% solution
- Calcipotriene 0.005% cream

### FDA Approved Indication(s)

- Indicated for treatment of plaque psoriasis (Funded by OHP in patients with severe disease)

### Dosing

- Apply a thin layer to the affected skin twice daily and rub in gently and completely

### Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, deny. Not funded by OHP

2. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
   - a. If yes, continue to #3
   - b. If no, deny. Medical appropriateness

3. Is calcipotriene 0.005% solution or cream being requested for plaque psoriasis or pityriasis rubra pilaris? (Provide supporting documentation)
   - a. If yes, continue to #4
   - b. If no, continue to #7

4. Does the member currently have severe inflammatory skin disease defined as having functional impairment (e.g. inability to use hands or feet or activies of daily living, or significant facial involvement preventing normal social interaction AND one or more of the following: At least 10% of body surface area involved AND/OR Hand, foot or mucous membrane involvement?
a. If yes, continue to #5
b. If, no, deny. Not funded by OHP

5. Has the member had 2 or more unsuccessful treatments with moderate to high potency corticosteroids? (E.g. betamethasone ointment/augmented cream, triamcinolone ointment, halobetasol, fluocinonide ointment/cream, etc.) (Provide supporting documentation)
   a. If yes, approve for 6 months
   b. If no, continue to #6

6. Does the member have a contraindication or is clinical rationale provided for avoiding moderate to high potency corticosteroids? (Provide supporting documentation)
   a. If yes, approve for 6 months
   b. If no, deny. Clinical criteria not met

7. Is the requested use of calcipotriene 0.005% solution/cream supported by major compendia? (Examples: Micromedex, Clinical Pharmacology, etc)
   a. If yes, continue to #8
   b. If no, deny. Medical appropriateness

8. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options for the requested indication? (Provide supporting documentation)
   a. If yes, continue to #9
   b. If no, deny. Clinical criteria not met

9. Is the requested treatment dose appropriate?
   a. If yes, continue to #10
   b. If no, deny. Medical appropriateness

10. Is the treatment being prescribed by or in consultation with an appropriate specialist?
    a. If yes, approve for 3 months
    b. If no, deny. Specialist consultation required
Note:
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:


Clobazam
Prior Authorization Guidelines

Affected Medication(s)

- Clobazam oral tablet
- Clobazam oral suspension

FDA Approved Indication(s)

- As adjunctive treatment for seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older

Dosing

- Starting dose: 5mg/day for patients 30 kg or less, 10mg/day in patients greater than 30 kg
- Maintenance dose: 20mg/day for patients 30 kg or less, 40mg/day in patients greater than 30 kg
- Doses greater than 5mg should be divided into twice daily dosing

Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request a renewal of a previously approved clobazam prior authorization and provided indication is the same as the previous approval?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Does the member have a diagnosis of Lennon-Gastaut syndrome (LGS)?
   a. If yes, continue to #4
   b. If no, deny. Clinical criteria not met

4. Is the member 2 years of age or older?
   a. If yes, continue to #5
5. Is the member currently taking at least one other antiepileptic drug with inadequate response? (i.e. valproic acid, lamotrigine, topiramate, felbamate) (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, deny. Clinical criteria not met

6. Will the member continue therapy with at least one other antiepileptic drug in combination with clobazam?
   a. If yes, continue to #7
   b. If no, deny. Clinical criteria not met

7. Is the medication prescribed by, or in consultation with, a neurologist?
   a. If yes, approve for 6 months
   b. If no, deny. Specialist consultation required

**Reauthorization Criteria**

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
   a. If yes, continue to #2
   b. If no, deny. Medical appropriateness

2. Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received? (Significant clinical response is defined by a decrease in seizure frequency compared to pre-treatment baseline) (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, deny. Required clinical information not received

3. Is the treatment being prescribed by, or in consultation with, a neurologist?
   a. If yes, approve for 12 months reauthorization
   b. If no, deny. Specialist consultation required

**Note:**

Last Reviewed: 1/22/19
Effective Date: 2/15/19
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

## Desmopressin acetate

### Prior Authorization Guidelines

**Affected Medication(s)**

- Desmopressin acetate oral tablet
- Desmopressin acetate nasal spray
- Desmopressin acetate subcutaneous solution

**FDA Approved Indication(s)**

**Oral Tablets:**

- As antidiuretic replacement therapy in the management of central diabetes insipidus and for the management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region
- Management of primary nocturnal enuresis (Non-funded condition)

**Nasal Spray:**

- As antidiuretic replacement therapy in the management of central diabetes insipidus in adults and pediatric patients 4 years of age and older

**Injection Solution:**

- For patients with hemophilia A with factor VIII coagulant activity levels greater than 5% (IV administration only, medical benefit)
- For patients with mild to moderate classic von Willebrand's disease (Type I) with factor VIII levels greater than 5% (IV administration only, medical benefit)
- As antidiuretic replacement therapy in the management of central (cranial) diabetes insipidus and for the management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region

**Dosing**

**Oral Tablets:**

- Recommended starting dose: 0.05 mg (½ of the 0.1 mg tablet) two times a day and individually adjusted to optimum therapeutic dose
- Total daily dosage should be increased or decreased in the range of 0.1 mg to 1.2 mg divided into two or three daily doses as needed to obtain adequate antidiuretic effect
Nasal Spray:
- Adults: 10 mcg once daily into one nostril up to 40 mcg once daily (or 40 mcg divided into two or three daily doses)
- Pediatrics 4 years of age and older: recommended starting does is 10 mcg once daily into one nostril. The dose can be titrated up to 30 mcg once daily (or 30 mcg divided into two daily doses, typically with 20 mcg given in the morning and 10 mcg given at nighttime).

Injection Solution: (Subcutaneous administration only)
- Usual dosage range in adults is 0.5 mL (2 mcg) to 1 mL (4 mcg) daily, administered subcutaneously, usually in two divided doses

**Initial Authorization Criteria**

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis) (Note: Primary nocturnal enuresis is not an above-the-line indication)
   a. If yes, continue to #2 
   b. If no, deny. Not funded by OHP

2. Is the request for renewal of a previously approved desmopressin acetate nasal spray, oral tablet, or injection solution prior authorization for the same indication as the previous approval?
   a. If yes, continue to Reauthorization 
   b. If no, continue to #3

3. Is desmopressin acetate being requested for treatment of central diabetes insipidus?
   a. If yes, continue to #4 
   b. If no, deny. Clinical criteria not met

4. Is the medication being administered through an intravenous route?
   a. If yes, deny. Intravenously administered medications are not covered under pharmacy benefit
   b. If no, continue to #5

5. Is this medication prescribed by, or in consult with, an endocrinologist?
Reauthorization Criteria

1. Is desmopressin acetate being requested for treatment of central diabetes insipidus?
   a. If yes, continue to #2
   b. If no, deny. Medical appropriateness

2. Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received? (i.e. control of nocturia associated with DI) (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, deny. Required clinical information not received

3. Is the treatment being prescribed by, or in consultation with, an endocrinologist?
   a. If yes, approve for 12 months reauthorization
   b. If no, deny. Specialist consultation required

Note:
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:


3. DDAVP (desmopressin acetate oral tablet) [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; January 2018
4. DDAVP (desmopressin acetate injection) [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; August 2018
# Epidiolex (cannabidiol)

## Prior Authorization Guidelines

### Affected Medication(s)

- Epidiolex (cannabidiol) oral solution

### FDA Approved Indication(s)

- Treatment of seizures associated with Lennon-Gastaut syndrome (LGS) or Dravet syndrome (DS)

### Dosing

- Starting dose: 2.5mg/kg taken twice daily for one week
- Maintenance dose: 5mg/kg twice daily up to maximum dose 10mg/kg twice daily

### Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request a renewal of a previously approved Epidiolex (cannabidiol) prior authorization and provided indication is the same as previous approval?
   
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Does the member have a diagnosis of Lennon-Gastaut syndrome (LGS) or Dravet syndrome (DS)?
   
   a. If yes, continue to #4
   b. If no, deny. Clinical criteria not met

4. Is the member 2 years of age or older?
   
   a. If yes, continue to #5
   b. If no, deny. Clinical criteria not met
5. Is the member currently taking at least one other antiepileptic drug with inadequate response? (i.e. valproic acid, lamotrigine, topiramate, felbamate) (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, deny. Clinical criteria not met

6. For members with LGS, has the member had a previous trial with inadequate response, intolerance, or contraindication to clobazam? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, deny. Clinical criteria not met

7. Will the member continue therapy with at least one other antiepileptic drug in combination with Epidiolex (cannabidiol)? (Provide supporting documentation)
   a. If yes, continue to #8
   b. If no, deny. Clinical criteria not met

8. Is the medication prescribed by, or in consultation with, a neurologist?
   a. If yes, approve for 6 months
   b. If no, deny. Specialist consultation required

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**Reauthorization Criteria**

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia?
   a. If yes, continue to #2
   b. If no, deny. Medical appropriateness

2. Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received? (Significant clinical response is defined by a decrease in seizure frequency compared to pre-treatment baseline) (Provide supporting documentation)
   a. If yes, continue to #3
b. If no, deny. Required clinical information not received

3. Is the treatment being prescribed by, or in consultation with, a neurologist?
   a. If yes, approve for 12 months reauthorization
   b. If no, deny. Specialist consultation required

Note:
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:
Fluticasone Propionate Nasal Spray  
Prior Authorization Guidelines

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
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<tbody>
<tr>
<td>• Fluticasone Propionate Nasal Spray</td>
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<tr>
<th>FDA Approved Indication(s)</th>
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<tbody>
<tr>
<td>• Allergic rhinitis and non-allergic rhinitis in adult and pediatric patients ages 4 years and older</td>
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<tr>
<th>Dosing</th>
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<tr>
<td>• One to two sprays per nostril once daily depending on age</td>
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<th>Initial Authorization Criteria</th>
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<tr>
<td>1. Is the diagnosis provided? (Provide documentation of diagnosis)</td>
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<tr>
<td>a. If yes, continue to #2</td>
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<tr>
<td>b. If no, deny. Documentation not received</td>
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<tr>
<td>2. Is the documented indication FDA approved or supported by major compendia?</td>
</tr>
<tr>
<td>a. If yes, continue to #3</td>
</tr>
<tr>
<td>b. If no, deny. Medical appropriateness</td>
</tr>
<tr>
<td>3. Does the member have co-morbid conditions funded by OHP? (i.e. chronic sinusitis, acute sinusitis, or sleep apnea) (Provide supporting documentation)</td>
</tr>
<tr>
<td>a. If yes, approve for 6 months for chronic sinusitis or sleep apnea and 1 month for acute sinusitis</td>
</tr>
<tr>
<td>b. If no, continue to #4</td>
</tr>
<tr>
<td>4. Does patient have a diagnosis of asthma or reactive airway disease in the past 1 year? (Provide supporting documentation)</td>
</tr>
<tr>
<td>a. If yes, continue to #5</td>
</tr>
<tr>
<td>b. If no, deny. Not funded by the OHP</td>
</tr>
</tbody>
</table>
5. Is there a claim for an orally inhaled corticosteroid in the past 90 days? (Provide documentation of medication history)
   a. If yes, deny. Medical appropriateness
   b. If no, approve for 6 months

Note:
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References:
# Galafold (migalastat hydrochloride)
## Prior Authorization Guidelines

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Galafold (migalastat hydrochloride) oral capsule</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FDA Approved Indication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 123 mg orally once every other day</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial Authorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)</td>
</tr>
<tr>
<td>a. If yes, continue to #2</td>
</tr>
<tr>
<td>b. If no, deny. Not funded by OHP</td>
</tr>
<tr>
<td>2. Is the request for use to treat an FDA approved indication?</td>
</tr>
<tr>
<td>a. If yes, continue to #3</td>
</tr>
<tr>
<td>b. If no, deny. Clinical criteria not met</td>
</tr>
<tr>
<td>3. Is the request a renewal of a previously approved Galafold (migalastat hydrochloride) prior authorization?</td>
</tr>
<tr>
<td>a. If yes, continue to Reauthorization</td>
</tr>
<tr>
<td>b. If no, continue to #4</td>
</tr>
<tr>
<td>4. Is the member 18 years of age or older?</td>
</tr>
<tr>
<td>a. If yes, continue to #5</td>
</tr>
<tr>
<td>b. If no, deny. Clinical criteria not met</td>
</tr>
</tbody>
</table>
5. Does the member have a diagnosis of Fabry disease that is confirmed by biochemical and/or molecular genetic testing? (i.e. kidney interstitial capillary cell globotriaosylceramide (KIC GL-3)) (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, deny. Clinical criteria not met

6. Does the member have a GLA variant based on in vitro assay that is considered amenable? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, deny. Clinical criteria not met

7. Is the member female?
   a. If yes, continue to #8
   b. If no, continue to #9

8. Does the member have documented clinical manifestations of Fabry disease? (Examples include: severe neuropathic/limb pain, telangiectasias, angiokeratomas, abdominal pain, nausea, vomiting, diarrhea, constipation, corneal opacities, proteinuria, polyuria, and polydipsia) (Provide supporting documentation)
   a. If yes, continue to #9
   b. If no, deny. Clinical criteria not met

9. Will Galafold (migalastat hydrochloride) be used in combination with other enzyme replacement therapy for treatment of Fabry disease? (i.e. fabrazyme)
   a. If yes, deny. Clinical criteria not met
   b. If no, continue to #10

10. Is the treatment being prescribed by, or in consultation with, a clinical geneticist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, deny. Clinical criteria not met

Reauthorization Criteria
1. Is the documented indication FDA approved or supported by major compendia?
   a. If yes, continue to #2
   b. If no, deny. Medical appropriateness

2. Has the member had a positive clinical response to therapy as defined as reduction in levels of kidney interstitial capillary cell globotriaosylceramide (KIC GL-3)? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, deny. Clinical criteria not met

3. Is the treatment being prescribed by, or in consultation with, a clinical geneticist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, deny. Clinical criteria not met

**Note:**
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**References:**

1. Galafold [Product Information], Amicus Therapeutics U.S., Inc. Cranbury, NJ. August 2018


Granulocyte Colony-Stimulating Factor (G-CSF)  
Prior Authorization Guidelines

### Affected Medication(s)
- Nivestym (filgrastim-aafi) injectable syringe
- Nivestym (filgrastim-aafi) injectable vial solution
- Fulphila (pegfilgrastim-jmdb) injectable syringe
- Udenyca (pegfilgrastim-cbqv) injectable syringe

### FDA Approved Indication(s)

**Nivestym:**
- To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
- To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation
- For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

**Fulphila and Udenyca:**
- To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia

### Dosing
- Indication-specific weight-based dosing, refer to package insert for details
Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the drug being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with an oncologist/hematologist or an appropriate specialist?
   a. If yes, continue to #4
   b. If no, clinical review required

4. What is the medication being requested for? (Provide supporting documentation)
   a. Bone Marrow Transplantation, approve for 4 months unless otherwise specified
   b. Peripheral Blood Progenitor cell (PBPC) mobilization, approve for 4 months unless otherwise specified
   c. Acute myeloid leukemia (AML) patient undergoing induction or consolidation chemotherapy, approve for 4 months unless otherwise specified
   d. Prophylaxis of febrile neutropenia in patients with non-myeloid malignancy, continue to corresponding criteria
   e. Treatment of chemotherapy-induced febrile neutropenia, continue to corresponding criteria
   f. Severe Chronic Neutropenia, continue to corresponding criteria
   g. Other indication, continue to corresponding criteria

Prophylaxis of febrile neutropenia in patients with non-myeloid malignancy

1. Does the planned chemotherapy regimen have a high risk (greater than 20% risk) of febrile neutropenia? (Provide supporting documentation)
2. Is the planned chemotherapy regimen for curative treatment intent? (Provide supporting documentation)
   
   a. If yes, continue to #4
   b. If no, continue to #3

3. Is clinical rationale provided to support the use of a high-risk regimen in the palliative setting? (Provide supporting documentation)
   
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member currently receiving concomitant chemotherapy and radiation therapy? (provide supporting documentation)
   
   a. If yes, clinical review required
   b. If no, approve for 4 months unless otherwise specified

5. Does the member have at least one of the following risk factors for febrile neutropenia? (provide supporting documentation)
   
   - 65 years or older and receiving full chemotherapy dose intensity
   - Prior chemotherapy or radiotherapy
   - Persistent neutropenia
   - Tumor involvement in the bone marrow
   - Recent surgery and/or open wounds
   - Renal dysfunction (creatinine clearance <50)
   - Liver dysfunction (bilirubin >2.0)

   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the planned chemotherapy regimen have an intermediate risk (10 to 20% risk) of febrile neutropenia? (Provide supporting documentation)
   
   a. If yes, continue to #7
b. If no, deny. Clinical criteria not met

7. Is the member currently receiving concomitant chemotherapy and radiation therapy? (Provide supporting documentation)
   a. If yes, clinical review required
   b. If no, approve for 4 months unless otherwise specified

**Treatment of chemotherapy-induced febrile neutropenia**

1. Has the member received a prophylaxis regimen for febrile neutropenia with filgrastim or sargramostim on the current chemotherapy cycle? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, continue to #3

2. Does the member have an absolute neutrophil count (ANC) <500/mm³? (Provide supporting documentation)
   a. If yes, approve for 1 month unless otherwise specified
   b. If no, clinical review required

3. Does the member have one or more of the following risk factors for developing infection-related complications? (provide supporting documentation)
   
   • Sepsis Syndrome
   • Age >65
   • Absolute neutrophil count [ANC] <100/mcL
   • Duration of neutropenia expected to be greater than 10 days
   • Pneumonia or other clinically documented infections
   • Invasive fungal infection
   • Hospitalization at the time of fever
   • Prior episode of febrile neutropenia

   a. If yes, approve for 1 month unless otherwise specified
   b. If no, clinical review required

**Severe chronic neutropenia**
1. Does the member have an absolute neutrophil count (ANC) <500/mm³? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a diagnosis of one of the following? (Provide supporting documentation)
   - Congenital neutropenia
   - Cyclic neutropenia
   - Idiopathic neutropenia
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have neutropenia symptoms? (i.e. fever, infections, etc.) (Provide supporting documentation)
   a. If yes, approve for 4 months unless otherwise specified
   b. If no, clinical review required

Other Indication
1. Is the requested use supported by major compendia? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options for the requested indication? (Provide supporting documentation)
   a. If yes, approve for 4 months unless otherwise specified
   b. If no, clinical review required

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do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:


Haegarda (human c1-esterase inhibitor)  
Prior Authorization Guidelines

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Haegarda (human c1-esterase inhibitor) subcutaneous injectable vial</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FDA Approved Indication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients. In clinical trials, Haegarda was studied in patients 12 and older.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 60IU/kg body weight subcutaneously twice weekly</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial Authorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)</td>
</tr>
<tr>
<td>a. If yes, continue to #2</td>
</tr>
<tr>
<td>b. If no, deny. Not funded by OHP</td>
</tr>
<tr>
<td>2. Is the request for renewal of a previously approved Haegarda (human c1-esterase inhibitor) prior authorization?</td>
</tr>
<tr>
<td>a. If yes, continue to Reauthorization</td>
</tr>
<tr>
<td>b. If no, continue to #3</td>
</tr>
<tr>
<td>3. Is the member avoiding possible triggers for HAE attacks? Possible triggers include:</td>
</tr>
<tr>
<td>- Helicobacter pylori infections (confirmed by lab test)</td>
</tr>
<tr>
<td>- Systemic estrogen products</td>
</tr>
<tr>
<td>- Antihypertensive agents containing ACE inhibitors</td>
</tr>
<tr>
<td>a. If yes, continue to #4 (Provide supporting documentation)</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td>4. Does the member have at least 2 HAE attacks per month at baseline? (Provide supporting documentation)</td>
</tr>
<tr>
<td>a. If yes, continue to #5</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
</tbody>
</table>
5. Does the member have a history of moderate to severe cutaneous or abdominal attacks OR mild to severe airway swelling attacks of HAE? (i.e. debilitating cutaneous/gastrointestinal symptoms OR laryngeal/pharyngeal/tongue swelling) (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the member have one of the following clinical presentations consistent with HAE subtype? (Provide supporting documentation)
   - For HAE I (C1-inhibitor deficiency):
     o Low C1 inhibitor (C1-INH) antigenic level (C1-INH antigenic level below the lower limit of normal as defined by the laboratory performing the test); AND
     o Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND
     o Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); AND
       ▪ Patient has a family history of HAE OR
       ▪ Normal C1q level
   - For HAE II (C1-inhibitor dysfunction):
     o Normal to elevated C1-INH antigenic level; AND
     o Low C4 level (C4 below the lower limit of normal as defined by the laboratory performing the test); AND
     o Low C1-INH functional level (C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the medication being prescribed by or in consultation with a specialist in allergy, immunology, hematology, pulmonology, or medical genetics?
   a. If yes, approve for 3 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Does the member continue to meet initial criteria above? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Has the member demonstrated significant improvement in severity and duration of attacks that has been achieved and sustained? (Provide supporting documentation)
   
a. If yes, continue to #3
b. If no, clinical review required

3. Is there documentation that there has been an absence of unacceptable toxicity from the drug? (Examples of unacceptable toxicity include the following: hypersensitivity reactions, serious thrombotic events, laryngeal attacks, etc) (Provide supporting documentation)
   
a. If yes, continue to #4
b. If no, clinical review required

4. Is the medication being prescribed by or in consultation with a specialist in allergy, immunology, hematology, pulmonology, or medical genetics?
   
a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

Note:
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References:


## Hepatitis C Agents
### Prior Authorization Guidelines

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Epclusa (sofosbuvir/velpatasvir) oral tablet</td>
</tr>
<tr>
<td>• Mavyret (glecaprevir/pibrentasvir) oral tablet</td>
</tr>
<tr>
<td>• Vosevi (sofosbuvir/velpatasvir/voxilaprevir) oral tablet</td>
</tr>
<tr>
<td>• Zepatier (elbasvir/grazoprevir) oral tablet</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FDA Approved Indication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>Epclusa</strong>: For the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis. For use in combination with ribavirin for decompensated cirrhosis</td>
</tr>
<tr>
<td>• <strong>Mavyret</strong>: 1. For treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). 2. For treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both</td>
</tr>
<tr>
<td>• <strong>Vosevi</strong>: For treatment of adult patients with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have 1. Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor. 2. Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. Additional benefit of Vosevi over Epclusa was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with Sovaldi without an NS5A inhibitor</td>
</tr>
<tr>
<td>• <strong>Zepatier</strong>: For treatment of adult patients with chronic hepatitis C virus (HCV) genotype type 1 or 4 infection. Also indicated to be use with ribavirin in certain patient population</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>Epclusa</strong>: One tablet (sofosbuvir 400mg/velpatasvir 100mg) once daily</td>
</tr>
<tr>
<td>• <strong>Mavyret</strong>: Three tablets (glecaprevir 100 mg/pibrentasvir 40mg) once daily</td>
</tr>
<tr>
<td>• <strong>Vosevi</strong>: One tablet (sofosbuvir 400 mg/velpatasvir 100 mg/ voxilaprevir 100mg) once daily</td>
</tr>
<tr>
<td>• <strong>Zepatier</strong>: One tablet (elbasvir 50mg/grazoprevir 100 mg) once daily</td>
</tr>
<tr>
<td>See recommended treatment regimen table below for regimen details and treatment duration</td>
</tr>
</tbody>
</table>
### Initial Authorization Criteria

1. **Is the diagnosis provided? (Provide documentation of diagnosis)**
   - a. Yes, go to #2
   - b. No, clinical review required

2. **Is the request for treatment of chronic Hepatitis C infection? (defined by positive HCV RNA detection in a patient with no suspicion of transmission in the previous 6 months OR persistent HCV detection for ≥6 months OR diagnosis of chronic viral hepatitis C (B18.2) for ≥6 months, OR positive HCV RNA with evidence of clinically significant fibrosis [≥F1]) (Provide supporting documentation)**
   - a. Yes, go to #3
   - b. No, clinical review required

3. **Is expected survival from non-HCV associated morbidities more than 1 year? (Provide supporting documentation)**
   - a. Yes, go to #4
   - b. No, clinical review required

4. **Have **ALL** of the following pre-treatment testing been completed? (Provide supporting documentation)**

   (Note: direct-acting antiviral agents can re-activate hepatitis B in some patients. Patients with history of HBV should be monitored carefully during and after treatment for flare-up of hepatitis. Prior to treatment with DAA, all patients should be tested for HBsAG, HBsAb, and HBcAB status.)

   - Genotype testing in past 3 years for patients with cirrhosis, patients with any prior treatment experience, and for regimens which are not pan-genotypic;
   - Baseline HCV RNA level in past 6 months
   - Current HIV status of patient
   - Current HBV status of patient
   - Pregnancy test in past 30 days for a woman of child-bearing age
   - History of previous HCV treatment and outcome
   - Presence or absence of cirrhosis as determined by clinical evidence of complications from cirrhosis, a serum test (FIBROSpect II; Fibrometer; enhanced liver fibrosis [ELF], Fibrosure), biopsy, OR imaging test (transient elastography [FibroScan®], acoustic radiation force impulse imaging [AFRI], or shear wave elastography [SWE]).

   - a. Yes, go to #5 (Note: if the patient has HIV or HBV co-infection, it is highly recommended that a specialist be consulted prior to treatment as treatment is not recommended during pregnancy due to lack of safety and efficacy data)
b. No, clinical review required

5. Is the planned treatment regimen and treatment duration provided? (Provide supporting documentation)
   
   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the member have clinical, radiologic or laboratory evidence of complications of cirrhosis (ascites, portal hypertension, hepatic encephalopathy, hepatocellular carcinoma, esophageal varices)? (Provide supporting documentation)
   
   a. Yes, go to #7
   b. No, go to #8

7. Is the regimen prescribed by, OR is the member in the process of establishing care with or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist?
   
   a. Yes, go to #7
   b. No, go to #8

8. Is there attestation that the member and provider will comply with all case management interventions to promote the best possible outcome for the member and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load? (Case management includes assessment of treatment barriers and offer of patient support to mitigate potential barriers to regimen adherence as well as facilitation of SVR12 evaluation to assess treatment success) (Provide supporting documentation)
   
   a. Yes, go to #7
   b. No, clinical review required

9. Is the prescribed drug: a) Elbasvir/grazoprevir for GT 1a infection; or b) Daclatasvir + sofosbuvir for GT 3 infection?
   
   a. Yes, go to #7
   b. No, go to #8

10. Has the member had a baseline NS5a resistance test that documents a resistant variant to one of the agents in #9? Note: baseline NS5A resistance testing is required (Provide supporting documentation)
    
    a. Yes, clinical review required
    b. No, go to #11 (document test and result)

11. Does the prescribed regimen include a NS3/4a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir)?
a. Yes, go to #12  
b. No, go to #13

12. Does the member have moderate-severe hepatitis impairment (Child-Pugh B or Child-Pugh C)?  (provide supporting documentation)  
   a. Yes, clinical review required  
   b. No, go to #13

13. Is the prescribed regimen for the re-treatment after failure of a DAA due to noncompliance or lost to follow-up?  
   a. Yes, clinical review required  
   b. No, go to #14

14. Is the prescribed drug regimen a recommended regimen based on the patient's genotype, treatment status (retreatment or treatment naive) and cirrhosis status (see Posted Criteria)? (provide supporting documentation)  
   a. Yes, approve for appropriate duration  
   b. No, clinical review required

Table 1: Recommended Treatment Regimens for Chronic Hepatitis C.

<table>
<thead>
<tr>
<th>Treatment History</th>
<th>Cirrhosis Status</th>
<th>Recommended Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genotype 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Treatment Naive</strong></td>
<td>Non-Cirrhotic</td>
<td>EBV/GZR x 12 weeks**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/VEL x 12 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G/P x 8 weeks</td>
</tr>
<tr>
<td></td>
<td>Compensated Cirrhosis</td>
<td>EBV/GZR x 12 weeks**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/VEL x 12 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G/P x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Decompensated Cirrhosis</td>
<td>SOF/VEL + RBV x 12 weeks</td>
</tr>
<tr>
<td><strong>Treatment Experienced</strong> (Prior PEG/RBV only)</td>
<td>Non-Cirrhotic</td>
<td>EBV/GZR x 12 weeks**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/VEL x 12 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G/P x 8 weeks</td>
</tr>
<tr>
<td></td>
<td>Compensated Cirrhosis</td>
<td>EBV/GRZ 12 weeks**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SOF/VEL x 12 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G/P x 12 weeks</td>
</tr>
<tr>
<td><strong>Treatment Experienced</strong> (Prior SOF)</td>
<td>Non-Cirrhotic or Compensated Cirrhosis</td>
<td>SOF/VEL x 12 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G/P x 12 weeks</td>
</tr>
<tr>
<td><strong>Treatment Experienced</strong> (Prior NS3A/4A inhibitor)</td>
<td>Non-Cirrhotic or Compensated Cirrhosis</td>
<td>SOF/VEL x 12 weeks</td>
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<td></td>
<td></td>
<td>EBV/GZR + RBV x 12 weeks**</td>
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<td></td>
<td></td>
<td>G/P x 12 weeks</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>Non-Cirrhotic or Compensated Cirrhosis</td>
<td>G/P x 16 weeks</td>
</tr>
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<tr>
<td><strong>Treatment Experienced (Prior NS5A-containing regimen)</strong></td>
<td>SOF/VEL x 12 weeks</td>
<td>G/P x 8 weeks</td>
</tr>
<tr>
<td><strong>Treatment Naive</strong></td>
<td>Non-Cirrhotic</td>
<td>SOF/VEL x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Compensated Cirrhosis</td>
<td>G/P x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Decompensated</td>
<td>SOF/VEL + RBV x 12 weeks</td>
</tr>
<tr>
<td><strong>Treatment Experienced (Prior PEG/RBV only)</strong></td>
<td>Non-Cirrhotic</td>
<td>SOF/VEL x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>Compensated Cirrhosis</td>
<td>G/P x 12 weeks</td>
</tr>
<tr>
<td><strong>Treatment Experienced (SOF + RBV)</strong></td>
<td>Non-Cirrhotic or Compensated Cirrhosis</td>
<td>SOF/VEL x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>SOF/VEL x 12 weeks</td>
<td>G/P x 12 weeks</td>
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<tr>
<td><strong>Treatment Experienced (prior NS5A-containing regimen)</strong></td>
<td>Non-Cirrhotic or Compensated Cirrhosis</td>
<td>SOF/VEL/VOX x 12 weeks</td>
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<table>
<thead>
<tr>
<th>Genotype 3</th>
<th>Non-Cirrhotic</th>
<th>SOF/VEL x 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment Naive</strong></td>
<td>Compensated Cirrhosis</td>
<td>SOF/VEL + RBV x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>G/P x 12 weeks</td>
<td>G/P x 16 weeks</td>
</tr>
<tr>
<td><strong>Treatment Experienced (Prior PEG/RBV only)</strong></td>
<td>Non-Cirrhotic or Compensated Cirrhosis</td>
<td>SOF/VEL x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>G/P x 16 weeks</td>
<td>G/P x 12 weeks</td>
</tr>
<tr>
<td><strong>Treatment Experienced (Prior SOF + RBV)</strong></td>
<td>Non-Cirrhotic or Compensated Cirrhosis</td>
<td>G/P x 16 weeks</td>
</tr>
<tr>
<td><strong>Experienced (prior NS5A-containing regimen)</strong></td>
<td>Non-Cirrhotic or Compensated Cirrhosis</td>
<td>SOF/VEL/VOX x 12 weeks</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Genotype 4</th>
<th>Non-Cirrhotic</th>
<th>SOF/VEL x 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment Naive</strong></td>
<td>Compensated Cirrhosis</td>
<td>SOF/VEL x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>EBV/GZR x 12 weeks</td>
<td>G/P x 8 weeks</td>
</tr>
<tr>
<td></td>
<td>Decompressed Cirrhosis</td>
<td>SOF/VEL + RBV x 12 weeks</td>
</tr>
<tr>
<td></td>
<td>EBV/GZR x 12 weeks</td>
<td>G/P x 12 weeks</td>
</tr>
</tbody>
</table>
| Treatment Experienced (Prior PEG/RBV only) | Non-Cirrhotic | SOF/VEL x 12 weeks  
EBV/GZR x 12 weeks  
G/P x 8 weeks  
Compensated Cirrhosis | SOF/VEL x 12 weeks  
EBV/GZR x 12 weeks  
G/P x 12 weeks  
Decompensated | SOF/VEL/VOX x 12 weeks |
|---|---|---|---|---|
| Treatment Experienced (Prior NS5A-containing regimen OR Non-Cirrhotic or Compensated Cirrhosis) | SOF/VEL/Vox x 12 weeks  
G/P x 12 weeks  
G/P x 12 weeks |

**Genotype 5/6**

| Treatment Naive or Experienced (Prior PED/RBV only) | Non-Cirrhotic | SOF/VEL x 12 weeks  
G/P x 8 weeks  
Compensated Cirrhosis | SOF/VEL x 12 weeks  
G/P x 12 weeks  
Decompensated | SOF/VEL + RBV x 12 weeks |
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<tbody>
<tr>
<td>Treatment Experienced (Prior NS5A-containing regimen OR Non-Cirrhotic or Compensated Cirrhosis)</td>
<td>SOF/VEL/VOX x 12 weeks</td>
<td></td>
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</tbody>
</table>

Abbreviations: CTP = Child-Turcotte-Pugh; DAA = direct acting antiviral; DCV = daclatasvir; EBV/GZR = elbasvir/grazoprevir; G/P = glecaprevir and pibrentasvir; PEG = pegylated interferon; RAV = resistance-associated variant; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir; SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir

**No baseline NS5A RAVs. For genotype 1a patients with baseline NS5A RAVs, extend duration to 16 weeks**

*Evidence is insufficient if the addition of RBV may benefit subjects with GT3 and cirrhosis. If RBV is not used with regimen, then baseline RAV testing should be done prior to treatment to rule out the Y93 polymorphism.

*Rarely, genotyping assays may indicate the presence of a mixed infection (e.g., genotypes 1a and 2). Treatment data for mixed genotypes with direct-acting antivirals are limited. However, in these cases, a pangenotypic regimen is appropriate.*

Ribavirin-containing regimens are absolutely contraindicated in pregnant women and in the male partners of women who are pregnant. Documented use of two forms of birth control in patients and sex partners for whom a ribavirin containing regimen is chosen is required.

Regimens other than glecaprevir/pibrentasvir (G/P) and elbasvir/grazoprevir (EBV/GZR) should not be used in patients with severe renal impairment (GFR < 30 mL/min) or end stage renal disease requiring dialysis.

All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C).

There is limited data supporting DAA regimen in treatment-experienced patients with decompenated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber and CCO or FFS medical director.

Note:
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References:


Increlex (mecasermin)
Prior Authorization Guidelines

Affected Medication(s)

- Increlex (mecasermin) subcutaneous vial solution

FDA Approved Indication(s)

- Treatment of growth failure in children with severe primary IGF-1 deficiency
- Treatment of growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH

Dosing

- Recommended starting dose: 0.04 to 0.08 mg/kg twice daily
- Maximum dose: 0.12 mg/kg twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request a renewal of a previously approved Increlex (mecasermin) prior authorization with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is the request for use to treat an FDA approved indication?
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have documentation of open epiphyses demonstrated on bone radiograph? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have any of the following secondary forms of IGF-1 deficiency? (Provide supporting documentation)
- Growth Hormone deficiency (GHD)
- Malnutrition
- Hypothyroidism
- Chronic treatment with pharmacologic doses of steroidal anti-inflammatories

  a. If yes, clinical review required
  b. If no, continue to #6

6. Is the medication being prescribed by, or in consultation with, a pediatric endocrinologist?

  a. If yes, continue to #7
  b. If no, clinical review required

7. What diagnosis is Increlex being requested for? (Provide supporting documentation)

  a. Severe IGF-1 deficiency, continue to corresponding criteria
  b. Growth hormone (GH) gene deletion, continue to corresponding

**Severe IGF-1 Deficiency**

1. Does the member have a height standard deviation score of less than or equal to -3.0? (Provide supporting documentation)

   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a basal IGF-1 standard deviation score of less than or equal to -3.0? (Provide supporting documentation)

   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have normal or elevated growth hormone levels? (Provide supporting documentation)

   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

**Growth hormone (GH) Gene Deletion**

1. Does the member have a basal IGF-1 level below normal range? (Provide supporting documentation)

   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member have a presence of neutralizing antibodies to GH as confirmed by serum testing or genetic testing? (Provide supporting documentation)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a positive clinical response to therapy as defined by a height velocity of at least 2cm per year? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Has the member met their expected adult height goal? (Provide supporting documentation)
   a. If yes, clinical review required
   b. If no, approve for 12 months unless otherwise specified

Note:
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References:

**Jynarque (tolvaptan)**

**Prior Authorization Guidelines**

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
</tr>
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<tbody>
<tr>
<td>• Jynarque (tolvaptan) oral tablet</td>
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<table>
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<tr>
<th>FDA Approved Indication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• To slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease</td>
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<thead>
<tr>
<th>Dosing</th>
</tr>
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<tbody>
<tr>
<td>• Initially: 60 mg orally per day as 45 mg taken on waking and 15 mg taken 8 hours later</td>
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<tr>
<td>• Titrate to 90 mg taken on waking and 30 mg taken 8 hours later if tolerated</td>
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<thead>
<tr>
<th>Initial Authorization Criteria</th>
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<tbody>
<tr>
<td>1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)</td>
</tr>
<tr>
<td>a. If yes, continue to #2</td>
</tr>
<tr>
<td>b. If no, deny. Not funded by OHP</td>
</tr>
<tr>
<td>2. Is the request for use to treat an FDA approved indication? (Provide supporting documentation)</td>
</tr>
<tr>
<td>a. If yes, continue to #3</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td>3. Is the request a renewal of a previously approved Jynarque (tolvaptan) prior authorization and the indication is for the same as previous approval?</td>
</tr>
<tr>
<td>a. If yes, continue to Reauthorization</td>
</tr>
<tr>
<td>b. If no, continue to #4</td>
</tr>
<tr>
<td>4. Is the member 18 years of age or older?</td>
</tr>
<tr>
<td>a. If yes, continue to #5</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td>5. Does the member have a diagnosis of autosomal dominant polycystic kidney disease confirmed by ultrasonography/ MRI/CT scan with at least two unilateral or bilateral cysts in patients with a family history of ADPKD, at least three unilateral or bilateral cysts in members with an unknown family history, AND/OR positive genetic testing? (Provide supporting documentation)</td>
</tr>
<tr>
<td>a. If yes, continue to #6</td>
</tr>
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Last Reviewed: 4/2/19
Effective Date: 5/1/19
6. Is the member at risk of rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) defined by any of the following? (Provide supporting documentation)
   - MAYO class 1C, 1D, or 1E
   - Total kidney volume (TKV) >750 mL
   - An ultrasound determined kidney length of > 16.5 cm
   - PROPKD score >6
   - Age of < 55 with CKD stage 3
   a. If yes, continue to #7
   b. If no, clinical review required

7. Does the member have a contraindication to Jynarque (tolvaptan)? (Contraindications include: History of signs or symptoms of significant liver impairment or injury, use of Jynarque with strong CYP 3A inhibitors (Examples: clarithromycin, nefazodone, ketoconazole, protease inhibitors, etc.), uncorrected abnormal blood sodium concentrations, unable to sense or respond to thirst, hypovolemia, uncorrected urinary outflow obstruction, or anuria) (Provide supporting documentation)
   a. If yes, clinical review required
   b. If no, clinical review required

8. Does the member have baseline liver function (ALT and AST) and bilirubin levels within normal range? (Provide supporting documentation)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Is the treatment being prescribed by or in consultation with a nephrologist?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Has the member had a positive clinical response to therapy as defined by a slowing in the decline in kidney function and/or an improvement in kidney pain? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member experienced an increase in ALT, AST, or bilirubin to greater than 2 times the upper limit of normal? (Provide supporting documentation)
   a. If yes, clinical review required
b. If no, continue to #3

3. Is the treatment being prescribed by or in consultation with a nephrologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

**Note:**

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

**References:**

Kalydeco (ivacaftor)
Prior Authorization Guidelines

Affected Medication(s)

- Kalydeco (ivacaftor) oral tablet
- Kalydeco (ivacaftor) oral granule packet

FDA Approved Indication(s)

- Treatment of cystic fibrosis (CF) in patients age 6 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data

Dosing

- For patients 6 years and older: One 150 mg tablet twice daily with fat-containing food
- For patients 6 months to less than 6 years:
  - 5 kg to less than 7 kg: One 25 mg packet twice daily
  - 7 kg to less than 14 kg: One 50 mg packet twice daily
  - 14 kg or greater: One 75 mg packet twice daily

Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request for renewal of a previously approved Kalydeco® (ivacaftor) prior authorization with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is Kalydeco® (ivacaftor) being requested for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have documentation of a cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation that is responsive to ivacaftor based on in vitro data and/or clinical data? (Provide supporting documentation)
   a. If yes, continue to #5

Last Reviewed: 10/18/18, 7/23/19
Effective Date: 11/15/18, 9/15/19
b. If no, clinical review required

5. Does the patient have documentation of baseline FEV1, ALT, and AST? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the patient at least 6 months of age?
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is Kalydeco® (ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis patient?
   a. If yes, approve for 6 months
   b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. improvement of FEV1 from baseline) (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Were updated chart notes (within past year) provided with documentation of follow up liver function tests? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is Kalydeco® (ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis patient?
   a. If yes, approve for 12 months
   b. If no, clinical review required
**Note:**

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**References:**

Kuvan (sapropterin)
Prior Authorization Guidelines

Affected Medication(s)

- Kuvan (sapropterin) oral tablet
- Kuvan (sapropterin) oral powder

FDA Approved Indication(s)

- To reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU)

Dosing

- Patients 1 month to 6 years: Starting dose of 10mg/kg once daily then dose adjust based on response
- Patients 7 years and older: Starting dose of 10 to 20 mg/kg once daily then dose adjust based on response

Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request a renewal of a previously approved Kuvan (sapropterin) prior authorization and provided indication is for same as previous approval?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is the request for use to treat an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Will Kuvan (sapropterin dihydrochloride) be used in conjunction with a phenylalanine-restricted diet (i.e. foods with high protein such as meat, fish, eggs, and milk products should be avoided)? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the baseline phenylalanine level provided? (Provide supporting documentation)
a. If yes, continue to #6
b. If no, clinical review required

6. Will the member have a phenylalanine blood level measured after 1 week of therapy and then periodically for up to 1 month of therapy? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the treatment being prescribed by or in consultation with a specialist experienced in treatment of hyperphenylalaninemia?
   a. If yes, approve for 2 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is Kuvan (sapropterin dihydrochloride) being used in conjunction with a phenylalanine-restricted diet (i.e. foods with high protein such as meat, fish, eggs, and milk products should be avoided)? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Has the member demonstrated a positive clinical response to therapy as defined by a decrease in average blood Phenylalanine levels by at least 30% below pretreatment baseline? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Will the member’s blood phenylalanine levels continue to be monitored throughout therapy? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the treatment being prescribed by or in consultation with a specialist experienced in treatment of hyperphenylalaninemia?
   a. If yes, approve for 12 months unless otherwise specified

b. If no, clinical review required

**Note:**

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**References:**


Lupron Depot- Ped (leuprolide acetate) 
Prior Authorization Guidelines

**Affected Medication(s)**
- Lupron Depot- Ped (leuprolide acetate) intramuscular injectable vial kit

**FDA Approved Indication(s)**
- Treatment of children with central precocious puberty (CPP)

**Dosing**
- For monthly administration:
  - <25 kg: 7.5 mg once monthly
  - >25 to 37.5 kg: 11.25 mg once monthly
  - >37.5 kg: 15 mg once monthly
- For every 3 months administration:
  - 11.25 mg or 30 mg every 3 months

**Initial Authorization Criteria**
1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP
2. Is the request for renewal of a previously approved Lupron (leuprolide acetate) prior authorization?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3
3. Is Lupron Depot-Ped (leuprolide acetate) being requested for an FDA approved or compendia supported indication (Examples include central precocious puberty and gender dysphoria)? (Provide supporting documentation)
   a. If yes, continue to corresponding diagnosis
   b. If no, clinical review required

**Central Precocious Puberty**
1. Is the member less than 8 years old if female or less than 9 years old if male?
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member have confirmation of diagnosis by measurement of serum luteinizing hormone (LH)? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the medication prescribed by, or in consultation with, a pediatric endocrinologist?
   a. If yes, continue to #3
   b. If no, clinical review required

Gender Dysphoria

1. Does the member have a diagnosis of gender dysphoria by a qualified mental health professional? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member 18 years of age or older?
   a. If yes, clinical review required
   b. If no, continue to #3

3. Does the member have Tanner stage 2 or later? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member a transgender female? (male to female)
   a. If yes, continue to #5
   b. If no, continue to #6

5. Has the member had a trial with inadequate response, an intolerance, or a contraindication to spironolactone? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is there documentation that the member demonstrated a knowledge and understanding of the expected outcomes and risks vs benefits of therapy? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the medication prescribed by, or in consultation with, an endocrinologist?
   a. If yes, approve for 6 months
b. If no, clinical review required

### Reauthorization Criteria

1. Is the documented indication approved by the FDA or compendia supported? (Provide supporting documentation)
   a. If yes, continue to corresponding criteria
   b. If no, clinical review required

#### Central Precocious Puberty

1. Does the member show a positive clinical response to therapy? (Examples include: adequate hormone suppression, cessation of menses in girls, normalization and stabilization of linear growth and bone age advancement, and stabilization in the clinical signs/symptoms of puberty) (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the medication being prescribed by, or in consultation with, a pediatric endocrinologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

#### Gender Dysphoria

1. Does the member show a positive clinical response to therapy as defined by achieving expected therapy outcome? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the medication being prescribed by, or in consultation with, an endocrinologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

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**Note:**

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References:

1. Lupron Depot- Ped [Product Information], AbbVie Inc. North Chicago, IL. November 2018


# MS Agents
## Prior Authorization Guidelines

### Affected Medication(s)
- Aubagio (teriflunomide) oral tablet
- Betaseron (interferon beta-1b) subcutaneous lyophilized powder
- Gilenya (fingolimod) oral capsule
- glatiramer acetate subcutaneous solution
- Plegridy (peginterferon beta-1a) subcutaneous solution
- Rebif (interferon beta-1a) subcutaneous solution
- Tecfidera (dimethyl fumarate) oral capsule

### FDA Approved Indication(s)
- **Aubagio**: For treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- **Betaseron**: For the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- **Gilenya**: For treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older
- **glatiramer acetate**: For treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- **Plegridy**: For treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- **Rebif**: For treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
- **Tecfidera**: For treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults

### Dosing
- Refer to corresponding package insert for dosing recommendations

### Initial Authorization Criteria
1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
b. If no, clinical review required

2. Is the request for renewal of a previously approved prior authorization for the same medication with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is an MRI result consistent with multiple sclerosis provided? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the request for Gilenya (fingolimod)?
   a. If yes, continue to #6
   b. If no, continue to #7

6. Does the member have one of the following contraindications to Gilenya (fingolimod)? (Provide supporting documentation)
   - Myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requires hospitalization or Class III/IV heart failure in the past 6 months
   - Mobitz Type II second-degree or third-degree AV block or sick sinus syndrome without a functioning pacemaker
   - Baseline QTc interval ≥ 500 msec
   - Concurrent use of Gilenya (fingolimod) with Class 1a or Class III anti-arrhythmic drugs

   a. If yes, clinical review required
   b. If no, continue to #7

7. Will the requested medication be used with other disease modifying therapy for multiple sclerosis? (Examples include Aubagio (teriflunomide), Lemtrada (alemtuzumab), Tecfidera (dimethyl fumarate), Gilenya (fingolimod), Glatopa (glatiramer acetate), interferon beta preparations, Tysabri (natalizumab), Ocrevus (ocrelizumab), etc.) (Provide supporting documentation)

   a. If yes, clinical review required
8. Is the medication being prescribed by or in consultation with a neurologist?
   a. If yes, approve for 12 months
   b. If no, clinical review required

## Reauthorization Criteria

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1.</td>
<td>Is the medication being requested for an FDA approved indication? (Provide supporting documentation)</td>
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<td></td>
<td>a. If yes, continue to #2</td>
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<td></td>
<td>b. If no, clinical review required</td>
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<tr>
<td>2.</td>
<td>Will the requested medication be used with other disease-modifying therapy for multiple sclerosis? (Examples include Lemtrada (alemtuzumab), Aubagio (teriflunomide), Tecfidera (dimethyl fumarate), Gilenya (fingolimod), Glatopa (glatiramer acetate), interferon beta preparations, Tysabri (natalizumab), Ocrevus (ocrelizumab), etc.) (Provide supporting documentation)</td>
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<tr>
<td></td>
<td>a. If yes, clinical review required</td>
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<td></td>
<td>b. If no, continue to #3</td>
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<td>3.</td>
<td>Is clinical documentation confirming responsiveness to therapy provided? (Confirm stable disease with slowed progression compared to pretreatment or no treatment) (Provide supporting documentation)</td>
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<td></td>
<td>a. If yes, continue to #4</td>
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<tr>
<td></td>
<td>b. If no, clinical review required</td>
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<tr>
<td>4.</td>
<td>Is the medication being prescribed by or in consultation with a neurologist?</td>
</tr>
<tr>
<td></td>
<td>a. If yes, approve for 12 months</td>
</tr>
<tr>
<td></td>
<td>b. If no, clinical review required</td>
</tr>
</tbody>
</table>

**Note:**

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

**References:**


# Mulpleta (Lusutrombopag) Prior Authorization Guidelines

## Affected Medication(s)
- Mulpleta (lusutrombopag) oral tablet

## FDA Approved Indication(s)
- Treatment of thrombocytopenia in adults with chronic liver disease scheduled to undergo procedure

## Dosing
- One-3mg tablet orally once daily, for seven days. Begin 8 to 14 days prior to scheduled procedure. Patients should undergo procedure 2 to 8 days after last dose

## Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, deny. Not funded by OHP

2. Is the request for use to treat an FDA approved indication?
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. Is the member 18 years of age or older?
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. Does the member have a platelet count of <50 x 10^9? (Provide supporting documentation)
   - a. If yes, continue to #5
   - b. If no, clinical review required

5. Does the member have a planned medical or dental procedure with intermediate-to-high bleeding risk within the next 30 days? (Examples include spinal surgery, cardiac surgery, large polypectomy, liver biopsy) (Provide supporting documentation)
   - a. If yes, continue to #6
   - b. If no, clinical review required
6. Is the treatment plan to begin therapy 8-14 days prior to the scheduled procedure and undergo the procedure 2-8 days after the last dose? (Examples include spinal/cardiac surgery, larger polypectomy, and liver biopsy) (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the treatment being prescribed by, or in consultation with, a hematologist, hepatologist, or gastroenterologist?
   a. If yes, approve for 7 days
   b. If no, clinical review required

**Note:**
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

**References:**
Norditropin (somatropin)  
Prior Authorization Guidelines

Affected Medication(s)

• Norditropin (somatropin) subcutaneous flexpro injectable

FDA Approved Indication(s)

• In pediatric patients with one of the following:
  o Growth failure due to inadequate secretion of endogenous growth hormone (GH)
  o Short stature associated with Noonan syndrome
  o Short stature associated with Turner syndrome
  o Small for gestational age (SGA) baby with no catch-up growth by age 2 years to 4 years of age (Non-funded condition)
  o Idiopathic Short Stature (ISS), height standard deviation score (SDS) <-2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range (Non-funded condition)
  o Growth failure due to Prader-Willi syndrome (PWS)

• In adult patients for the replacement of endogenous GH in adults with growth hormone deficiency (GHD) (Non-funded condition)

NOTE: Growth hormone deficiency without short stature is not a funded indication. Both adult and pediatric indications are not funded once adult height is reached as determined by bone age.

Dosing

• In pediatrics:
  o Pediatric GH Deficiency: 0.17 mg/kg/week to 0.24 mg/kg/week (0.024 to 0.034 mg/kg/day)
  o Noonan Syndrome: Up to 0.46 mg/kg/week (up to 0.066 mg/kg/day)
  o Turner Syndrome: Up to 0.47 mg/kg/week (up to 0.067 mg/kg/day)
  o Small for Gestational Age (SGA): Up to 0.47 mg/kg/week (up to 0.067 mg/kg/day)
    ▪ In very short pediatric patients, HSDS less than -3, and older pubertal pediatric patients consider initiating treatment with a larger dose of NORDITROPIN (up to 0.067 mg/kg/day). Consider a gradual reduction in dosage if substantial catch-up growth is observed during the first few years of therapy. In pediatric patients less than 4 years of age with less severe short stature, baseline HSDS values between -2 and -3, consider initiating treatment at 0.033 mg/kg/day and titrate the dose as needed.
  o Idiopathic Short Stature: Up to 0.47 mg/kg/week (up to 0.067 mg/kg/day)
  o Prader-Willi Syndrome: 0.24 mg/kg/week (0.034 mg/kg/day)
• In adults:
  o Non-weight based: Initiate at 0.2 mg/day (range, 0.15 mg/day to 0.3 mg/day) and increase the
dose every 1-2 months by increments of approximately 0.1 mg/day to 0.2 mg/day OR
  o Weight-based: Initiate at 0.004 mg/kg daily and increase the dose according to individual
  patient requirements to a maximum of 0.016 mg/kg daily

**Initial Authorization Criteria**

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of
diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request a renewal of a previously approved Norditropin (somatropin) prior authorization for
   the same indication as previous approval?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is the requested medication being prescribed by, or in consultation with, and endocrinologist?
   a. If yes, continue to #4
   b. If no, clinical review required

4. What is the diagnosis that Norditropin (somatropin) is being requested for? (Provide supporting
documentation)
   a. Short stature due to growth failure due to growth hormone deficiency (GHD) in pediatrics,
      continue to corresponding criteria
   b. Growth failure due to Prader-Willi Syndrome (PWS) in pediatrics, continue to corresponding
      criteria
   c. Short stature associated with Turner's Syndrome (TS) in pediatrics, continue to corresponding
      criteria
   d. Short stature associated with Noonan Syndrome (NS) in pediatrics, continue to corresponding
      criteria

**Growth hormone deficiency (GHD) in pediatrics**

1. Does the member have auxologic evidence of short stature by one of the following? (Provide
   supporting documentation)
   • “Severe” short stature (height < −3 SD below mean for age)
   • Height < −1.5 SD below mid-parental height (average of mother’s/father’s
     heights)
• Height < −2 SD below mean for bone age AND a 1-year height velocity < −1 SD below the mean for chronologic age or (in children 2 years of age or older) a 1-year decrease of > 0.5 SD in height
  
a. If yes, continue to #2  
b. If no, clinical review required

2. Does the member have a diagnosis of GHD confirmed by any of the following? (Provide supporting documentation)
   • Insulin-like growth factor 1 (IGF-1) and insulin-like growth factor binding protein-3 (IGFBP-3) are <−2 SD with delayed bone age  
   • Positive for PROP1 or POU1F1 mutation  
   • When newborn, history of hypoglycemia, serum GH concentration <5 mcg/L, and deficiency ≥ 1 other pituitary hormone  
   • Known pituitary abnormality (e.g. congenital anomaly, tumor, irradiation) and deficiency ≥ 1 other pituitary hormone
  
a. If yes, continue to #5  
b. If no, continue to #3

3. Has the member completed GH stimulation testing? (Provide supporting documentation)
   
a. If yes, continue to #4  
b. If no, clinical review required

4. Upon provocative testing, was GH < 10 mcg/L for two different stimuli? (Provide supporting documentation)
   
a. If yes, continue to #5  
b. If no, clinical review required

5. Have other causes of short stature or growth failure been ruled out? (i.e. hypothyroidism, chronic systemic disease, and/or skeletal disorders) (Provide supporting documentation)
   
a. If yes, continue to #6  
b. If no, clinical review required

6. Is there documentation of open epiphyses? (Provide supporting documentation)
   
a. If yes, approve for 6 months unless otherwise specified  
b. If no, clinical review required

Prader-Willi Syndrome (PWS) in pediatrics

1. Does the member have a diagnosis of PWS confirmed by genetic testing? (Provide supporting documentation)
<p>| | |</p>
<table>
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</thead>
</table>
| 1. | Does the member have a diagnosis of TS confirmed by karyotype analysis? (Provide supporting documentation)  
| a. | If yes, continue to #2  
| b. | If no, clinical review required  
| 2. | Is the member’s height below the 5th percentile of the normal female growth curve? (Provide supporting documentation)  
| a. | If yes, continue to #3  
| b. | If no, clinical review required  
| 3. | Is the member 2 years of age or older?  
| a. | If yes, continue to #4  
| b. | If no, clinical review required  
| 4. | Is there documentation of open epiphyses? (Provide supporting documentation)  
| a. | If yes, approve for 6 months unless otherwise specified  
| b. | If no, clinical review required  |

Turner’s Syndrome (TS) in pediatrics

1. Does the member have a diagnosis of TS confirmed by karyotype analysis? (Provide supporting documentation)  
   a. If yes, continue to #2  
   b. If no, clinical review required  

2. Does the member have uncontrolled diabetes, severe obesity, severe sleep apnea, or respiratory compromise? (Provide supporting documentation)  
   a. If yes, clinical review required  
   b. If no, continue to #3  

3. Does the member have evidence of short stature or growth failure as defined as any of the following? (Provide supporting documentation)  
   a. Height < −1.5 SD below mid-parental height (average of mother's/father's heights)  
   b. Height < −2 SD below mean of same gender and chronological age  
   c. Height velocity < −2 SD below mean over 1 year OR < −1.5 SD below mean over 2 years  
   a. If yes, continue to #4  
   a. If no, clinical review required  

4. Is there documentation of open epiphyses? (Provide supporting documentation)  
   a. If yes, continue to #4  
   a. If no, clinical review required  

Turner’s Syndrome (TS) in pediatrics

1. Does the member have a diagnosis of TS confirmed by karyotype analysis? (Provide supporting documentation)  
   a. If yes, continue to #2  
   b. If no, clinical review required  

2. Is the member’s height below the 5th percentile of the normal female growth curve? (Provide supporting documentation)  
   a. If yes, continue to #3  
   b. If no, clinical review required  

3. Is the member 2 years of age or older?  
   a. If yes, continue to #4  
   b. If no, clinical review required  

4. Is there documentation of open epiphyses? (Provide supporting documentation)  
   a. If yes, approve for 6 months unless otherwise specified  
   b. If no, clinical review required
Noonan Syndrome in pediatrics

1. Does the member have Noonan syndrome confirmed by genetic testing? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have short stature with height < −2 SD below mean of same gender and chronological age? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Has severe hypertrophic cardiomyopathy been ruled out? (Examples of probable HCM include an abnormal electrocardiogram, an echocardiography showing left ventricle hypertrophy or systolic anterior motion of the mitral valve, or abnormal exercise testing) (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Has the member been screened for thyroid abnormalities? (Examples include autoimmune thyroiditis with presence of thyroid autoantibodies) (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is there documentation of open epiphyses? (Provide supporting documentation)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Is Norditropin (somatropin) being requested for one of the following conditions? (Provide supporting documentation)
   - Short stature due to growth failure due to growth hormone deficiency (GHD) in pediatrics, continue to corresponding criteria
   - Growth failure due to Prader-Willi Syndrome (PWS) in pediatrics, continue to corresponding criteria
   - Short stature associated with Turner's Syndrome (TS) in pediatrics, continue to corresponding criteria
• Short stature associated with Noonan Syndrome (NS) in pediatrics, continue to corresponding criteria
  a. If yes, continue to #2
  b. If no, clinical review required

2. Is there documentation of the member responding to therapy (i.e. growth velocity ≥ 2 cm/year)? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member still have potential to grow (i.e. has not reached expected final adult height)? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member’s IGF-I level maintained between 0 to +2 SD for age? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is there documentation of open epiphyses? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the requested medication being prescribed by, or in consultation with, and endocrinologist?
   a. If yes, approve for 12 months
   b. If no, clinical review required

Note:
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:


## Oncology Policy
### Prior Authorization Guidelines

### Affected Medication(s)

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
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<tbody>
<tr>
<td>abiraterone acetate tablet</td>
<td>Ninlaro (ixazomib capsule)</td>
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<tr>
<td>Afinitor (everolimus oral tablet)</td>
<td>Odomzo (sonidegib capsule)</td>
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<td>Afinitor Disperz (everolimus tablet for suspension)</td>
<td>Pomalyst (pomalidomide capsule)</td>
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<td>Piqray (alpelisib daily dose)</td>
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<td>Alunbrig (brigatinib oral tablet)</td>
<td>Revlimid (lenalidomide capsule)</td>
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<td>Bosulif (bosutinib oral tablet)</td>
<td>Rubraca (rucaparibib tablet)</td>
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<td>Braftovi (encorafenib)</td>
<td>Rydapt (midostaurin capsule)</td>
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<td>Sprycel (dasatinib tablet)</td>
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<td>Cometrix (caboazentinib oral capsule)</td>
<td>Sutent (sunitinib malate capsule)</td>
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<td>Copiktra (duvelisib oral capsule)</td>
<td>Tafinlar (dabrafenib mesylate capsule)</td>
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<td>Tagrisso (osimertinibib tablet)</td>
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<td>Mekinist (tramezinib dimethyl sulfoxide tablet)</td>
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<td>Nerlynx (neratinib tablet)</td>
<td>Zykadia (ceritinib capsule)</td>
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</table>

Last Reviewed: 11/26/19
Effective Date: 1/1/20
## FDA Approved Indication(s)

- Refer to major compendia for supported use

## Dosing

- Refer indication specific compendia supported dosing

## Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   
   a. If yes, continue to #2
   
   b. If no, clinical review required

2. Is the request for continuation of therapy with the same anti-cancer medication?
   
   a. If yes, continue to **Reauthorization**
   
   b. If no, continue to #3

3. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)
   
   a. If yes, continue to #5
   
   b. If no, continue to #4

4. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) recommendation with an evidence level of 2A or higher? (Provide disease staging, all prior treatment history, pathology report, and anticipated treatment plan for review)
   
   a. If yes, continue to #5
   
   b. If no, clinical review required

5. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide supporting documentation)
   
   a. If yes, continue to #6
   
   b. If no, clinical review required

6. Is the medication being prescribed by, or in consultation with, an oncologist?
   
   a. If yes, approve for 4 months
   
   b. If no, clinical review required
### Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by NCCN recommendation with an evidence level of 2A or higher? (Provide supporting documentation)
   - a. If yes, continue to #2
   - b. If no, clinical review required

2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Example include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with an oncologist?
   - a. If yes, approve for 12 months
   - b. If no, clinical review required

### Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

### References:


53. VERZENIO (abemaciclib) oral tablet [package insert]. Indianapolis, IN: Lilly USA, LLC.; September 2019.


Last Reviewed: 11/26/19
Effective Date: 1/1/20
**Orkambi (lumacaftor/ivacaftor)  
Prior Authorization Guidelines**

### Affected Medication(s)
- Orkambi (lumacaftor/ivacaftor) oral tablet
- Orkambi (lumacaftor/ivacaftor) oral granule packet

### FDA Approved Indication(s)
- Treatment of cystic fibrosis (CF) in patients age 2 years and older who are homozygous for the F508del mutation in the CFTR gene

### Dosing
- For patients 2-5 years old weighing less than 14 kg: One packet of Orkambi® (lumacaftor 100mg/ivacaftor 125mg) granules every 12 hours with fat-containing food
- For patients 2-5 years old weighing 14 kg or greater: One packet of Orkambi® (lumacaftor 150mg/ivacaftor 188mg) granules every 12 hours with fat-containing food
- For patients 6-11 years old: Two Orkambi® (lumacaftor 100mg/ivacaftor 125mg) tablets every 12 hours with fat containing food
- For patients 12 years and older: Two Orkambi® (lumacaftor 200mg/ivacaftor 125mg) tablets every 12 hours with fat containing food

### Initial Authorization Criteria
1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request for renewal of a previously approved Orkambi® (lumacaftor/ivacaftor) prior authorization with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is Orkambi® (lumacaftor/ivacaftor) being requested for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Does the patient have a documentation of homozygous F508del mutation by a FDA-cleared CF mutation test? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Does the patient have documentation of baseline FEV1, ALT, and AST? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required
6. Is the patient at least 2 years of age?
   a. If yes, continue to #7
   b. If no, clinical review required
7. Is Orkambi® (lumacaftor/ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis patient?
   a. If yes, approve for 6 months
   b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. improvement of FEV1 from baseline) (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Were updated chart notes (within past year) provided with documentation of follow up liver function tests? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is Orkambi® (lumacaftor/ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis patient?
   a. If yes, approve for 12 months
b. If no, clinical review required

**Note:**
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

**References:**

# Oxervate (cenegermin-bkbj) Prior Authorization Guidelines

## Affected Medication(s)

- Oxervate (cenegermin-bkbj) eye drop solution

## FDA Approved Indication(s)

- Treatment of neurotrophic keratitis

## Dosing

- One drop in affected eye(s) 6 times per day for 8 weeks

## Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member aged 2 years or older?
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have a diagnosis of neurotrophic keratitis (NK) stage 2 or stage 3? (Characterized as persistent corneal epithelial defect and/or corneal stroma involvement with presence corneal ulcer) (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Has the member trialed both preservative-free artificial tears and topical antibiotic eye drops with inadequate response? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Has the member previously been treated with a course of Oxervate for the same eye? (Note: Retreatment with Oxervate is not supported)
   a. If yes, clinical review required
   b. If no, continue to #6
6. Is the medication being prescribed by, or in consultation with, an ophthalmologist?
   a. If yes, approve for 8 weeks (Note: no more of 8 weeks per eye may be approved. Treatment beyond 8 weeks has not been studied)
   b. If no, clinical review required

Note:
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:
Pulmonary Arterial Hypertension (PAH) Agents
Prior Authorization Guidelines

Affected Medication(s)
- sildenafil 20 mg oral tablet
- bosentan oral tablet

FDA Approved Indication(s)
- **Sildenafil 20 mg oral tablet**: Treatment of pulmonary arterial hypertension (PAH, WHO Group 1) in adults to improve exercise ability and delay clinical worsening
- **Bosentan**: Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) in adults to improve exercise ability and to decrease clinical worsening. Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) in pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR)

Dosing
- Sildenafil: 20 mg orally three times daily
- Bosentan: Weight based dosing taken orally twice daily. Refer to package insert for specific dosing information

Initial Authorization Criteria
1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP
2. Is the request for renewal of a previously approved authorization for use in pulmonary arterial hypertension?
   a. If yes, continue to **Reauthorization**
   b. If no, continue to #3
3. Is the medication being prescribed for an FDA approved indication? (Provide supporting documentation) (Note: sildenafil 20 mg is not FDA approved for erectile dysfunction)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the request for use to treat PAH World Health Organization (WHO) Group 1? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Has the diagnosis been confirmed by right heart catheterization demonstrating mPAP > 25 mmHg, PVR > 3 Wood units, and PCWP <15 mmHg (or confirmed Pby another recommended test such as echocardiograph if catheterization cannot be performed)? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the member have WHO or New York Heart Association (NYHA) Functional Class II-IV symptoms? (Symptoms include shortness of breath and/or fatigue during moderate exertion or stress, shortness of breath and/or fatigue during minimal exertion, or an inability to carry out physical activity) (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the prescriber an appropriate specialist (i.e. pulmonologist or cardiologist)?
   a. If yes, continue to #8
   b. If no, clinical review required

8. Is sildenafil the requested medication?
   a. If yes, continue to #9
   b. If no, continue to #11

9. Does the member currently take other organic nitrates in any form, regularly or intermittently? (Examples include isosorbide dinatirate, isosorbide mononitrate, and nitroglycerin) (Provide supporting documentation)
   a. If yes, clinical review required
   b. If no, continue to #10

10. Will the medication be used concomitantly with Adempas (riociguat)?
    a. If yes, clinical review required
    b. If no, approve for 6 months
11. Does the member have documentation of inadequate response, contraindication, or intolerance to a PDE5 inhibitor for treatment of PAH (e.g. sildenafil 20 mg)? (Provide supporting documentation)
   a. If yes, continue to #12
   b. If no, clinical review required

12. Is the member a female with reproductive potential?
   a. If yes, continue to #13
   b. If no, continue to #14

13. Has a pregnancy test been obtained within 30 days prior to start of treatment to exclude pregnancy? (Provide supporting documentation)
   a. If yes, continue to #14
   b. If no, clinical review required

14. Does the member have preexisting moderate or severe hepatic impairment? (Provide supporting documentation)
   a. If yes, clinical review required
   b. If no, continue to #15

15. Will Bosentan be used concurrently with cyclopentolate or glyburide?
   a. If yes, clinical review required
   b. If no, approve for 6 months

Reauthorization Criteria

1. Is the request for use to treat an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member demonstrated a positive clinical response to therapy? (Examples include improvement in 6-minute walking distance and/or stabilization or improvement in WHO functional class) (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the prescriber a relevant specialist (i.e. pulmonologist or cardiologist)?
   a. If yes, approve for 12 months unless
   b. If no, clinical review required
Note:

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

1. Revatio (sildenafil) [package insert]. NY, NY: Pfizer Labs; February 2019
## Palynziq (pegvaliase-pqpz) Prior Authorization Guidelines

### Affected Medication(s)
- Palynziq (pegvaliase-pqpz) subcutaneous syringe

### FDA Approved Indication(s)
- To reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management

### Dosing
- Initial recommended dose: 2.5mg subcutaneously once weekly for four weeks.
- Titrate dosage in step-wise manner over at least five weeks to achieve a dosage of 20mg one time daily, based on tolerability

### Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request a renewal of a previously approved Palynziq (pegvaliase-pqpz) prior authorization and provided indication is the same as previous approval?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is the member 18 years of age or older?
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have a blood phenylalanine concentration of 600 micromol/L or greater? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Has the member had a trial with inadequate response to a phenylalanine-restricted diet and does the treatment plan include continuation of a phenylalanine-restricted diet in combination with Palynziq

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Last Reviewed: 1/22/19  
Effective Date: 2/15/19
(pegvaliase-pqpz)? (i.e. foods with high protein such as meat, fish, eggs, and milk products should be avoided) (Provide supporting documentation)

a. If yes, continue to #6
b. If no, clinical review required

6. Has the member had a previous trial with inadequate response (defined as continued increased blood phenylalanine concentration), intolerance, or contraindication to treatment with Kuvan (sapropterin)? (Provide supporting documentation)

a. If yes, continue to #7
b. If no, clinical review required

7. Does the treatment plan include monitoring blood phenylalanine concentration at least every 4 weeks until a maintenance dose is established? (Provide supporting documentation)

a. If yes, continue to #8
b. If no, clinical review required

8. Is the treatment being prescribed by or in consultation with a specialist experienced in treatment of hyperphenylalaninemia?

a. If yes, approve for 4 months unless otherwise specified
b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide supporting documentation)

a. If yes, continue to #2
b. If no, clinical review required

2. Were updated chart notes (within 1 year) provided with documentation of significant clinical response to therapy defined as a reduction in the blood phenylalanine level of at least 20% from pretreatment baseline or a blood phenylalanine level of 600 micromol/L or less? (Provide supporting documentation)

a. If yes, continue to #3
b. If no, clinical review required

3. Is the treatment being prescribed by or in consultation with a specialist experienced in treatment of hyperphenylalaninemia?

a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required
Note:
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:


Affected Medication(s)

- Praluent subcutaneous solution
- Repatha subcutaneous solution

FDA Approved Indication(s)

**Praluent:**
- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease
- As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C)

**Repatha:**
- In adults with established cardiovascular disease, REPATHA is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization
- As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C)
- As an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C

Dosing

- **Praluent:** 75 mg subcutaneously every 2 weeks
- **Repatha:** 420 mg subcutaneously once monthly

Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request for a renewal of a previously approved PCSK9 inhibitor prior authorization for the same indication?
a. If yes, continue to Reauthorization
b. If no, continue to #3

3. Is the requested medication being used for an FDA-approved indication? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the request for Praluent?
   a. If yes, continue to #5
   b. If no, continue to #6

5. Does the member have a previous trial with inadequate response, intolerance, or contraindication to treatment with Repatha? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Are all of the following provided? (Provide supporting documentation)
   • Complete lipid panel performed within the last 3 months
   • Baseline LDL-C (untreated)
   • Documentation of dietary measures being undertaken to lower cholesterol
   a. If yes, continue to #7
   b. If no, clinical review required

7. What is the diagnosis that the PCSK9 inhibitor is being requested for?
   a. Heterozygous or Homozygous familial hypercholesterolemia (HeFH/HoFH), continue to #8
   b. Hypercholesterolemia with history of clinical atherosclerotic cardiovascular disease (ASCVD), continue to #10

8. Is pre-treatment LDL-cholesterol received (within 3 months) with baseline LDL-C greater than 190 mg/dL or greater than 155 mg/dL if less than 16 years of age? (Provide supporting documentation)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Does the member meet at least one of the following? (Provide supporting documentation)
   • Family History of myocardial infarction before age 60 years in first-degree relative
   • Family History of myocardial infarction before age 50 years in second-degree relative
- Family History of LDL-C greater than 190 mg/dL in a first- or second-degree relative
- Tendinous xanthomata and/or arcus cornealis in first-degree relative or documented during physical examination
- Functional mutation of LDL receptor, apoB, OR PCSK9 gene confirmed by genetic testing
  a. If yes, continue to #12
  b. If no, clinical review required

10. Is pre-treatment LDL-cholesterol received (within 3 months) greater than 100 mg/dL? (Provide supporting documentation)
  a. If yes, continue to #11
  b. If no, clinical review required

11. Does the member have atherosclerotic cardiovascular disease (ASCVD) confirmed by at least one of the following? (Provide supporting documentation)
  - Acute coronary syndromes
  - History of myocardial infarction
  - Stable or unstable angina
  - Coronary or other arterial revascularization
  - Stroke
  - Transient ischemic attack
  - Peripheral arterial disease presumed to be of atherosclerotic origin
  a. If yes, continue to #12
  b. If no, clinical review required

12. Is the Member currently receiving high-intensity statin therapy for a consecutive 3 months and will continue with high-intensity statin therapy? (High-intensity statin therapy includes: atorvastatin 40-80 mg or rosuvastatin 20-40 mg) (Provide supporting documentation)
  a. If yes, continue to #17
  b. If no, continue to #13

13. What is the rationale provided for avoiding high-intensity statin therapy? (Provide supporting documentation)
  a. Statin intolerance due to myalgia or myopathy, continue to # 14
  b. History of rhabdomyolysis with creatinine kinase (CK) levels greater than 10-times upper limit of normal (document date occurred), continue to #16
  c. Labeled contraindication to all statins, continue to #16
### Reauthorization Criteria

1. Is the request for use to treat an FDA-approved indication? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is an updated lipid panel with confirmation of significant reduction in LDL defined as a decrease in LDL levels of at least 40% from pre-treatment levels provided? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with cardiologist, endocrinologist, or lipid specialist?
   a. If yes, approve for 12 months, unless otherwise specified
   b. If no, clinical review required

<table>
<thead>
<tr>
<th>Question</th>
<th>Action</th>
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</table>
| 14. Is the member currently receiving a maximally tolerated dose of a statin AND ezetimibe and will continue statin and ezetimibe with PCSK9? (Provide supporting documentation) | a. If yes, continue to #17  
   b. If no, continue to #15   |
| 15. Is documentation of persistent myalgia or myopathy on 2 separate 8-week trials with pravastatin, rosvastatin, or fluvastatin provided? | a. If yes, continue to #16  
   b. If no, clinical review required |
| 16. Has the member been on ezetimibe for 3 consecutive months and will continue concurrently with PCSK9? (Provide supporting documentation) | a. If yes, continue to #17  
   b. If no, clinical review required |
| 17. Is the medication being prescribed by or in consultation with cardiologist, endocrinologist, or lipid specialist? | a. If yes, approve for 12 months, unless otherwise specified  
   b. If no, clinical review required |
Note:
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References:

Pregabalin
Prior Authorization Guidelines

Affected Medication(s)

- Pregabalin oral capsule

FDA Approved Indication(s)

- Management of neuropathic pain associated with diabetic peripheral neuropathy
- Management of postherpetic neuralgia
- Adjunctive therapy for treatment of partial onset seizures in patients 4 years of age and older
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

Dosing

- Diabetic peripheral neuropathy: Maximum 300 mg per day
- Fibromyalgia: Maximum 450 mg per day
- Postherpetic neuralgia, seizures, neuropathic pain associated with spinal cord injury: Maximum 600 mg per day

Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request for renewal of a previously approved Lyrica (pregabalin) prior authorization with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is Lyrica (pregabalin) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Did the member have an inadequate response to a 3 month trial of gabapentin? (Provide supporting documentation)
a. If yes, approve for 3 months
b. If no continue to #5

5. Does the member have a history of intolerance or contraindication to gabapentin? (Provide supporting documentation)
   a. If yes, approve for 3 months
   b. If no, clinical review required

<table>
<thead>
<tr>
<th>Reauthorization Criteria</th>
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<tbody>
<tr>
<td>1. Is Lyrica (pregabalin) being requested for an FDA approved or major compendia supported indication? (Provide supporting documentation)</td>
</tr>
<tr>
<td>a. If yes, continue to #2</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td>2. Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received? (Provide supporting documentation)</td>
</tr>
<tr>
<td>a. If yes, approve for 12 months</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
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Note:
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References:

## Affected Medication(s)
- Prevymis oral tablet
- Prevymis intravenous solution

## FDA Approved Indication(s)
- Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)

## Dosing
- 480 mg once daily through day 100 post-transplantation

## Initial Authorization Criteria
1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is Prevymis (letermovir) being requested for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is Prevymis (letermovir) being initiated immediately after OR within 28 days of transplant?
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member meet one of the following criteria? 1) CMV-seropositive recipient 2) CMV-seronegative recipient receiving a graft from seropositive donor (CMV D+/R-) who received an HLA-1mismatched allograft, an umbilical cord blood allograft, or alemtuzumab (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Is documentation with rationale for avoidance or contraindication to both ganciclovir and valganciclovir received? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Has the current medication list been reviewed by the care team confirming no major drug interaction with Prevymis? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the treatment being prescribed by or in consultation with a hematologist/oncologist, transplant specialist, or infectious disease specialist?
   a. If yes, approve for 4 months
   b. If no, clinical review required

Note:
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:
### Promacta

**Prior Authorization Guidelines**

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
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<tbody>
<tr>
<td>• Promacta oral tablet</td>
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<tr>
<td>• Promacta oral suspension packet</td>
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<tr>
<th>FDA Approved Indication(s)</th>
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<tbody>
<tr>
<td>• Treatment of thrombocytopenia in adult and pediatric patients 1 years and older with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy</td>
</tr>
<tr>
<td>• Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy</td>
</tr>
<tr>
<td>• Treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy</td>
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<th>Dosing</th>
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<tbody>
<tr>
<td>• For ITP:</td>
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<tr>
<td>o Adult and pediatric 6 years and older: Initially 50 mg once daily (if East Asian ancestry or Child-Pugh Class A, B, or C reduce dose to 25mg once daily, reduce to 12.5 mg once daily if patient is both)</td>
</tr>
<tr>
<td>o Pediatric patients 1-5 years old: Initially 25 mg once daily</td>
</tr>
<tr>
<td>o For both pediatric and adult patients, adjust dose as outlined in Package insert with a max of 75 mg/day</td>
</tr>
<tr>
<td>• For Chronic Hepatitis C-associated thrombocytopenia: Initially 25 mg once daily. Adjust as outlined in package insert, not exceeding a dose of 100 mg daily</td>
</tr>
<tr>
<td>• For severe aplastic anemia: Initially 50 mg once daily (if East Asian ancestry or Child-Pugh Class A, B, or C reduce dose to 25mg once daily). Adjust as outlined in package insert, not exceeding a dose of 150mg daily</td>
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</tbody>
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<tr>
<th>Initial Authorization Criteria</th>
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<tbody>
<tr>
<td>1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)</td>
</tr>
<tr>
<td>a. If yes, continue to #2</td>
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<tr>
<td>b. If no, deny. Not funded by OHP</td>
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Last Reviewed: 10/18/18
Effective Date: 11/15/18
2. Is the request for renewal of a previously approved Promacta® (eltrombopag) prior authorization with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. What is the diagnosis that Promacta® (eltrombopag) is being requested for?
   a. Chronic immune (idiopathic) thrombocytopenia (ITP), continue to corresponding criteria
   b. Chronic hepatitis C-associated thrombocytopenia, continue to corresponding criteria
   c. Severe aplastic anemia, continue to corresponding criteria

### Chronic immune (idiopathic) thrombocytopenia (ITP)

1. Is the patient’s platelet count less than 30 x 10⁹/L (30,000/mm)? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has patient previously tried and failed glucocorticoids AND splenectomy or rituximab (Failure defined as platelet count fails to reach greater than or equal to 50 x 10⁹/L (50,000/mm))? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with a hematologist?
   d. If yes, approve for 3 months
   e. If no, clinical review required

### Chronic hepatitis C-associated thrombocytopenia

1. Is the patient’s platelet count less than 75 x 10⁹/L (75,000/mm)? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is there documentation of compensated liver disease (Defined as Child-Pugh Class A)? (Provide supported lab for review)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with a hepatologist or ID specialist?
   a. If yes, approve for 2 months
b. If no, clinical review required

**Aplastic anemia**

1. Is the patient’s platelet count less than $30 \times 10^9/L$ (30,000/mm$^3$)? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the patient tried and failed at least one prior immunosuppressive therapy (Example: cyclosporine)? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with an infectious disease specialist?
   a. If yes, approve for 4 months
   b. If no, clinical review required

**Reauthorization Criteria**

1. Is the documented indication approved by the FDA or supported by major compendia? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the medication being prescribed by or in consultation with an appropriate specialist?
   a. If yes, continue to #3
   b. If no, clinical review required

3. What is the diagnosis that Promacta® (eltrombopag) is being requested for? (Record submitted diagnosis and review all criteria based on the submitted diagnosis)
   a. Chronic immune (idiopathic) thrombocytopenia (ITP), continue to #4
   b. Chronic hepatitis C-associated thrombocytopenia, continue to #5
   c. Severe aplastic anemia, continue to #6

4. Were updated chart notes (within previous 6 months) provided with documentation of significant clinical response to prior therapy received? (i.e. platelet count greater than or equal to $50 \times 10^9/L$ (50,000/mm$^3$))? (Provide supporting documentation)
   a. If yes, approval for 12 months
b. If no, clinical review required

5. Were updated chart notes (within previous 6 months) provided with documentation of significant clinical response to prior therapy received? (i.e. platelet count greater than or equal to 90 x 10^9/L (90,000/mm))? (Provide supporting documentation)
   a. If yes, approval for 12 months
   b. If no, clinical review required

6. Were updated chart notes (within previous 6 months) provided with documentation of significant clinical response to prior therapy received? (i.e. one of the following: platelet count increases to 20 x 10^9/L above baseline, stable platelet counts without transfusion for 8 or more weeks, hemoglobin increases by > 1.5 g/dL, ANC increases 100%, or ANC increase > 0.5 x10^9/L) (Provide supporting documentation)
   a. If yes, approval for 12 month
   b. If no, clinical review required

Note:
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References:
1. Promacta® (eltrombopag) [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline LLC. August 2015.
Retacrit (epoetin alfa-epbx)
Prior Authorization Guidelines

Affected Medication(s)

• Retacrit (epoetin alfa-epbx) subcutaneous solution
• Retacrit (epoetin alfa-epbx) intravenous solution

FDA Approved Indication(s)

• Treatment of anemia in patients with chronic kidney disease (CKD) to decrease the need for red blood cell (RBC) transfusion
• Treatment of anemia due to zidovudine administered at ≤ 4200 mg/week in patients with HIV-infection with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL
• Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy
• To reduce the need for allogeneic red blood cell (RBC) transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, non-cardiac, nonvascular surgery (Note: Epoetin alfa is not indicated for patients who are willing to donate autologous blood pre-operatively)

Dosing

• Refer to Package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request for renewal of a previously approved Retacrit (epoetin alfa-epbx) prior authorization with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. Is the medication being requested for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #4
b. If no, clinical review required

4. Have serum ferritin, transferrin saturation, hemoglobin (Hb), and hematocrit (Hct) labs been completed within 30 days of planned administration? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have a serum ferritin $ \geq 100$ ng/mL (mcg/L) and transferrin saturation (TSAT) $\geq 20\%$? (Review serum ferritin and transferrin saturation lab values) (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the member have a hemoglobin (hB) $< 10$ g/dL and/or Hematocrit (Hct) $< 30\%$? (Review hemoglobin and/or hematocrit lab values) (Provide supporting documentation)
   a. If yes, continue to #8
   b. If no, continue to #7

7. Is the medication being requested to reduce allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery? (Provide supporting documentation)
   a. If yes, continue to #8
   b. If no, clinical review required

8. Have other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) been ruled out? (Provide supporting documentation)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Which indication is Retacrit (epoetin alfa-epbx) being requested for?
   a. Anemia secondary to myelodysplastic syndrome (MDS), continue to corresponding criteria
   b. Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis, continue to corresponding criteria
   c. Anemia secondary to rheumatoid arthritis, approve for 45 days unless otherwise specified
   d. Anemia secondary to chemotherapy treatment, continue to corresponding criteria
   e. Anemia secondary to chronic kidney disease (non-dialysis patients), approve for 45 days unless otherwise specified
   f. Anemia secondary to zidovudine treated, HIV-infected patients, continue to corresponding criteria
g. Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery, continue to corresponding criteria
h. Anemia of Prematurity, continue to corresponding criteria
i. Other Indication, continue to corresponding criteria

Anemia secondary to myelodysplastic syndrome (MDS)

1. Does the member have symptomatic anemia? (Examples: exertional dyspnea, dyspnea at rest, fatigue, lethargy, confusion, etc.) (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member’s endogenous serum erythropoietin level ≤ 500 mUnits/mL? (Provide supporting documentation)
   a. If yes, approve for 45 days unless otherwise specified
   b. If no, clinical review required

Anemia secondary to Myeloproliferative Neoplasms (MPN) – Myelofibrosis

1. Is the member’s endogenous serum erythropoietin level < 500 mUnits/mL? (Provide supporting documentation)
   a. If yes, approve for 45 days unless otherwise specified
   b. If no, clinical review required

Anemia secondary to chemotherapy treatment

1. Is the member receiving concurrent myelosuppressive chemotherapy for non-myeloid malignancies? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the therapy intention of the chemotherapy curative? (Provide supporting documentation)
   a. If yes, clinical review required
   b. If no, continue to #3

3. Are there two or more additional months of planned chemotherapy remaining? (Provide supporting documentation)
a. If yes, approve for 45 days unless otherwise specified  
b. If no, clinical review required

**Anemia secondary to zidovudine treated, HIV-infected patients**

1. Does the member have an endogenous serum erythropoietin level ≤ 500 mUnits/mL OR is the member currently receiving zidovudine administered at ≤ 4200 mg/week? (Provide supporting documentation)  
   a. If yes, approve for 45 days unless otherwise specified  
   b. If no, clinical review required

**Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery**

1. Does the member have a hemoglobin (Hb) level between 10 g/dL and 13 g/dL and/or is the hematocrit (Hct) between 30% and 39%? (Provide supporting documentation)  
   a. If yes, approve for 45 days unless otherwise specified  
   b. If no, clinical review required

**Anemia of Prematurity**

1. Is Epogen/Procrit (apoetin alfa) being used in combination with iron supplementation? (Provide supporting documentation)  
   a. If yes, approve for 45 days unless otherwise specified  
   b. If no, clinical review required

**Other Indications**

1. Is the requested use supported by major compendia? (Provide supporting documentation)  
   a. If yes, continue to #2  
   b. If no, clinical review required

2. Has the member tried and had an inadequate response OR dose the member have a contradiction to ALL standard treatment options for the requested indication? (Provide supporting documentation)  
   a. If yes, approve for 45 days unless otherwise specified  
   b. If no, clinical review required
# Reauthorization Criteria

1. Is Retacrit (epoetin alfa-epbx) being requested for an FDA approved indication? (Provide supporting documentation)
   
   a. If yes, continue to #2
   b. If no, clinical review required

2. Was the last dose of Retacrit (epoetin alfa-epbx) less than 60 days ago? (Provide supporting documentation)
   
   a. If yes, continue to #3
   b. If no, clinical review required

3. Were updated chart notes (within 1 year) provided with documentation of significant clinical response to therapy? (Provide supporting documentation)
   
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is there documentation of an absence of unacceptable toxicity from the drug? (Examples include severe cardiovascular events (stroke, myocardial infarction, thromboembolism, uncontrolled hypertension), tumor progression or recurrence in members with cancer, seizures, pure red cell aplasia, severe cutaneous reactions (erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis), “gasing syndrome” (central nervous system depression, metabolic acidosis, gasping respirations) due to benzyl alcohol preservative, etc) (Provide supporting documentation)
   
   a. If yes, continue to #5
   b. If no, clinical review required

5. Were lab values obtained within 30 days of the date of administration (unless otherwise indicated)? (Provide supporting documentation)
   
   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the member have adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months? (Provide supporting documentation)
   
   a. If yes, continue to #7
   b. If no, clinical review required
7. Have other causes of anemia (e.g. hemolysis, bleeding, vitamin deficiency, etc.) been ruled out? (Provide supporting documentation)
   a. If yes, continue to #8
   b. If no, clinical review required

8. Does the member meet the clinical requirements for their corresponding diagnosis as defined below? (Provide supporting documentation)
   - Anemia secondary to myelodysplastic syndrome (MDS) with Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36%
   - Anemia secondary to myeloproliferative neoplasms (MF, post-PV myelofibrosis, post-ET myelofibrosis) with Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30%
   - Reduction of allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery with Hemoglobin (Hb) between 10 g/dL and 13 g/dL and/or Hematocrit (Hct) between 30% and 39%
   - Anemia secondary to palliative myelosuppressive chemotherapy for non-myeloid malignancies with Hemoglobin (Hb) < 10 g/dL and/or Hematocrit (Hct) < 30% and requesting epoetin alfa to be used concurrently with chemotherapy with minimum two additional months of therapy remaining
   - Anemia secondary to zidovudine treated, HIV-infected patients with Hemoglobin (Hb) < 12 g/dL and/or Hematocrit (Hct) < 36% AND receiving zidovudine administered at ≤ 4200 mg/week
   - Anemia secondary to chronic kidney disease with hemoglobin (Hb) < 12 g/dL and/or hematocrit (Hct) < 36% in pediatric patients OR hemoglobin (Hb) < 11 g/dL and/or hematocrit (Hct) < 33% in adult patients
   - Hemoglobin (Hb) < 11 g/dL and/or Hematocrit (Hct) < 33% for all other indications
   a. If yes, approve for 45 days unless otherwise specified
   b. If no, clinical review required

Note:
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References:
# Stimate

## Prior Authorization Guidelines

### Affected Medication(s)

- Stimate nasal spray

### FDA Approved Indication(s)

- For patients with hemophilia A with Factor VIII coagulant activity levels greater than 5%
- For patients with mild to moderate classic von Willebrand's disease (Type I) with Factor VIII levels greater than 5%

### Dosing

- One spray per nostril (total dose of 300 mcg)
- For patients <50kg, one single spray may be used (total dose of 150 mcg)
- If used pre-operatively, administered 2 hours prior to procedure

### Initial Authorization Criteria

1. Is the submitted diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, deny. Not funded by OHP

2. Is the request for renewal of a previously approved Stimate (desmopressin acetate nasal spray) prior authorization for the same indication as the previous approval?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #3

3. Does the member have a diagnosis of hemophilia A (factor VIII deficiency)? (Provide supporting documentation)
   - a. If yes continue to corresponding criteria
   - b. If no, continue to #4

4. Does the member have a diagnosis of von Willebrand disease type 1? (Provide supporting documentation)
   - a. If yes, continue to corresponding criteria
   - b. If no, clinical review required
Hemophilia A (factor VIII deficiency)

1. Is the member 2 years of age or older?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is Stimate being requested for treatment or prevention of bleeding? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have a factor VIII level greater than 5%? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have factor VIII antibodies? (Provide supporting documentation)
   a. If yes, clinical review required
   b. If no, continue to #5

5. Is this medication prescribed by, or in consult with, a hematologist?
   a. If yes, approve for 6 months
   b. If no, clinical review required

Von Willebrand Disease

1. Is the member 2 years of age or older?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is Stimate being requested for the treatment or prevention of bleeding? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have a factor VIII level greater than 5%? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is this medication prescribed by, or in consult with, a hematologist?
   a. If yes, approve for 6 months
**Reauthorization Criteria**

1. **Is the documented indication FDA approved or supported by major compendia?** (Provide supporting documentation)
   - a. If yes, continue to #2
   - b. If no, clinical review required

2. **Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received?** (i.e. hemostasis, control of bleeding episodes) (Provide supporting documentation)
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. **Is the treatment being prescribed by, or in consultation with, a hematologist?**
   - a. If yes, approve for 12 months reauthorization
   - b. If no, clinical review required

**Note:**

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**References:**

## Symdeko (tezacaftor/ivacaftor)
### Prior Authorization Guidelines

### Affected Medication(s)
- Symdeko oral tablet

### FDA Approved Indication(s)
- Treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence

### Dosing
- Tezacaftor 100 mg/ivacaftor 150 mg orally in the morning and ivacaftor 150 mg in the evening, approximately 12 hours apart

### Initial Authorization Criteria
1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, deny. Not funded by OHP
2. Is the request for renewal of a previously approved Symdeko® (tezacaftor/ivacaftor) prior authorization with the same indication?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #3
3. Is Symdeko® (tezacaftor/ivacaftor) being requested for an FDA approved indication? (Provide supporting documentation)
   - a. If yes, continue to #4
   - b. If no, clinical review required
4. Does the patient have a documentation of homozygous F508del mutation by a FDA-cleared CF mutation test? (Provide supporting documentation)
   - a. If yes, continue to #6
   - b. If no, continue to #5
5. Does the patient have documentation of at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical data? (Provide supporting documentation)


a. If yes, continue to #6
b. If no, clinical review required

6. Does the member have documentation of trial with insufficient response, intolerance, or contraindication to Orkambi®? (Provide supporting documentation)

a. If yes, continue to #7
b. If no, clinical review required

7. Is the patient at least 12 years of age?

a. If yes, continue to #8
b. If no, clinical review required

8. Does the patient have documentation of baseline FEV1, ALT, and AST? (Provide supporting documentation)

a. If yes, continue to #9
b. If no, clinical review required

9. Is Symdeko® (tezacaftor/ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis patient?

a. If yes, approve for 6 months
b. If no, clinical review required

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Reauthorization Criteria

1. Is the documented indication approved by the FDA? (Provide supporting documentation)

a. If yes, continue to #2
b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of significant clinical response to prior therapy received? (i.e. improvement of FEV1 from baseline) (Provide supporting documentation)

a. If yes, continue to #3
b. If no, clinical review required

3. Were updated chart notes (within past year) provided with documentation of follow up liver function tests? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is Symdeko® (tezacaftor/ivacaftor) being prescribed by, or in consult with, a pulmonologist or a provider at a cystic fibrosis center?
   a. If yes, approve for 12 months
   b. If no, clinical review required

Note:
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References:


Synagis (palivizumab)
Prior Authorization Guidelines

**Affected Medication(s)**
- Synagis intramuscular injection

**FDA Approved Indication(s)**
- Prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:
  - With a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of RSV season
  - With bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of RSV season
  - With hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of RSV season

**Dosing**
- 15 mg per kg of body weight given monthly by intramuscular injection
  - The first dose of Synagis should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season

**Initial Authorization Criteria**

1. Is the submitted diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, deny. Not funded by OHP

2. Is the request for a compendia supported indication? (Provide supporting documentation)
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. Is the member's weight provided for review?
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. Does the member have a history of hospitalization for RSV infection during the current RSV season? (Provide supporting documentation)
5. What indication is Synagis being requested for?
   a. Premature birth, continue to corresponding criteria
   b. Chronic lung disease of prematurity, continue to corresponding criteria
   c. Hemodynamically significant congenital heart disease, continue to corresponding criteria
   d. Anatomic pulmonary abnormalities or neuromuscular disorder, continue to corresponding criteria
   e. Immunocompromised, continue to corresponding criteria
   f. Cystic fibrosis, continue to corresponding criteria

Premature Birth

1. Does the member have a history of premature birth defined as less than 29 weeks gestation? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member less than 12 months of age at the start of RSV season?
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the treatment plan include 5 or less doses of Synagis? (Provide supporting documentation)
   a. If yes, approve for up to 5 doses during RSV season
   b. If no, clinical review required

Chronic Lung Disease of Prematurity

1. Does the member have a history of premature birth defined as gestational age of less than 32 weeks gestation? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a diagnosis of chronic lung disease as defined by a requirement for >21% oxygen for at least 28 days after birth? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the member < 12 months old at the start of RSV season?
   a. If yes, approve for up to 5 doses
   b. If no, continue to #4

4. Is the member <24 months old at the start of RSV season?
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have a continued requirement for medical support including chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen within 6 months of the start of RSV season? (Provide supporting documentation)
   a. If yes, approve for up to 5 doses during RSV season
   b. If no, clinical review required

### Hemodynamically Significant Congenital Heart Disease

1. Is the member <12 months of age at onset of RSV season?
   a. If yes, continue to #2
   b. If no, continue to #5

2. Does the member have a diagnosis of acyanotic heart disease and is receiving medication to control congestive heart failure and will require a cardiac surgical procedure? (Provide supporting documentation)
   a. If yes, approve for up to 6 doses
   b. If no, continue to #3

3. Does the member have a diagnosis of moderate to severe pulmonary hypertension? (Provide supporting documentation)
   a. If yes, approve for up to 5 doses during the RSV season
   b. If no, continue to #4

4. Does the member have a diagnosis of cyanotic heart defect and RSV prophylaxis is recommended by a pediatric cardiologist? (Provide supporting documentation)
   a. If yes, approve up to 5 doses during RSV season
   b. If no, clinical review required

5. Is the member <24 months of age at onset of RSV season?
   a. If yes, continue to #6
b. If no, clinical review required

6. Does the member have a history of cardiopulmonary bypass during the RSV season? (Provide supporting documentation)
   a. If yes, approve up to 6 doses during RSV season
   b. If no, clinical review required

Anatomic Pulmonary Abnormalities or Neuromuscular Disorder

1. Is the member <12 months of age at the onset of RSV season?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a diagnosis of a neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway? (e.g. ineffective cough) (Provide supporting documentation)
   a. If yes, approve for up to 5 doses during RSV season
   b. If no, clinical review required

Immunocompromised

1. Is the member <24 months of age at the onset of RSV season?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Will the member continue to be profoundly immunocompromised during the RSV season? (Examples include: solid organ or hematopoietic stem cell transplantation, chemotherapy administration, or immunocompromising disease) (Provide supporting documentation)
   a. If yes, approve for up to 5 doses during RSV season
   b. If no, clinical review required

Cystic Fibrosis

1. Is the member <12 months of age at the onset of RSV season?
   a. If yes, continue to #2
   b. If no, continue to #3
2. Does the member have CLD of prematurity (defined as gestational age <32 weeks and a requirement for >21% oxygen for at least 28 days after birth) and/or nutritional compromise (i.e. tube feeding requirement)? (Provide supporting documentation)
   a. If yes, approve for up to 5 doses during RSV season
   b. If no, clinical review required

3. Is the member <24 months of age at the onset of RSV season?
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have manifestations of severe lung disease as defined by previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography/chest computed tomography that persist when member is not experiencing exacerbation? (Provide supporting documentation)
   a. If yes, approve for up to 5 doses during RSV season
   b. If no, continue to #5

5. Does the member have a weight for length that is < 10th percentile? (Provide supporting documentation)
   a. If yes, approve for up to 5 doses during RSV season
   b. If no, clinical review required

Note:
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References:
## Tacrolimus ointment
### Prior Authorization Guidelines

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
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<tbody>
<tr>
<td>Tacrolimus topical ointment</td>
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<tr>
<th>FDA Approved Indication(s)</th>
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<tbody>
<tr>
<td><strong>Atopic dermatitis:</strong> indicated for treatment of moderate to severe atopic dermatitis in immunocompetent patient not responsive to conventional therapy or when conventional therapy is not appropriate; funded by OHP in patient with severe disease</td>
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<tr>
<td><strong>Oral lichen planus (off-label):</strong> funded by OHP in patient with severe disease</td>
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<tr>
<td><strong>Psoriasis (off-label):</strong> funded by OHP</td>
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<tr>
<td><strong>Pyoderma gangrenosum (off-label):</strong> funded by OHP</td>
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<tr>
<td><strong>Vitiligo (off-label):</strong> not funded by OHP</td>
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<table>
<thead>
<tr>
<th>Dosing</th>
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<tbody>
<tr>
<td><strong>0.03% ointment for children 2 years of age and up; 0.1% ointment for adults only</strong></td>
</tr>
<tr>
<td><strong>Atopic dermatitis:</strong> apply a thin layer to the affected skin twice daily</td>
</tr>
<tr>
<td><strong>Psoriasis:</strong> apply thin layer of 0.03% ointment twice daily</td>
</tr>
<tr>
<td><strong>Oral lichen planus:</strong> apply a thin layer of 0.1% ointment to affected area up to 4 times daily</td>
</tr>
<tr>
<td><strong>Pyoderma gangrenosum:</strong> apply thin layer of 0.1% or 0.3% ointment to affected area once daily</td>
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<thead>
<tr>
<th>Initial Authorization Criteria</th>
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<tbody>
<tr>
<td><strong>1.</strong> Is the submitted diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)</td>
</tr>
<tr>
<td>a. If yes, continue to #2</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td><strong>2.</strong> Is the documented indication Food and Drug Administration (FDA) approved or supported by major compendia? (Provide supporting documentation)</td>
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<tr>
<td>a. If yes, continue to #3</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td><strong>3.</strong> Is tacrolimus ointment being requested for one of the following conditions? (Provide supporting documentation)</td>
</tr>
<tr>
<td>• <strong>Atopic dermatitis</strong></td>
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<tr>
<td>• <strong>Psoriasis</strong></td>
</tr>
</tbody>
</table>
- Lichen planus
  a. If yes, continue to #4
  b. If no, continue to #7

4. Does the member currently have severe inflammatory skin disease defined as having functional impairment (e.g. inability to use hands or feet or activities of daily living, or significant facial involvement preventing normal social interaction AND one or more of the following: At least 10% of body surface area involved AND/OR Hand, foot or mucous membrane involvement? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, deny. Not funded by OHP

5. Has the member had 2 or more unsuccessful treatments with moderate to high potency corticosteroids? (E.g. betamethasone ointment/augmented cream, triamcinolone ointment, halobetasol, fluocinonide ointment/cream, etc.) (Provide supporting documentation)
   a. If yes, approve for 6 months
   b. If no, continue to #6

6. Does the member have a contraindication or clinical rationale for avoiding moderate to high potency corticosteroids? (Provide supporting documentation)
   a. If yes, approve for 6 months
   b. If no, clinical review required

7. Is the requested use of tacrolimus ointment supported by major compendia? (Examples: Micromedex, Clinical Pharmacology, etc) (Provide supporting documentation)
   a. If yes, continue to #8
   b. If no, clinical review required

8. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options for the requested indication? (Provide supporting documentation)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Is the requested treatment dose appropriate? (Provide supporting documentation)
   a. If yes, continue to #10
   b. If no, clinical review required
10. Is the treatment being prescribed by or in consultation with an appropriate specialist?
   a. If yes, approve for 3 months
   b. If no, clinical review required

**Note:**
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

**References:**

Therapeutic Immunomodulators
Prior Authorization Guidelines

Affected Medication(s)

- Actemra (tocilizumab) subcutaneous solution
- Cimzia (certolizumab) subcutaneous solution
- Cosentyx (secukinumab) subcutaneous solution
- Enbrel (etanercept) subcutaneous solution
- Humira (adalimumab) subcutaneous solution
- Otezla (apremilast) oral tablet

FDA Approved Indication(s)

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<tr>
<th>Medication</th>
<th>RA</th>
<th>JIA</th>
<th>PsA</th>
<th>AS</th>
<th>Crohn</th>
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<th>Ps</th>
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Dosing

- Refer to corresponding package insert for information

Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, deny. Not funded by OHP

2. Is the request for renewal of therapeutic immunomodulatory therapy prior authorization previously approved for the same indication?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #3

3. Will the requested medication be used concurrently with other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Humira, Otelza, Cosentyx, etc.)
   - a. If yes, clinical review required
   - b. If no, continue to #4
4. What is the diagnosis that the medication is being requested for?
   a. Rheumatoid arthritis (RA), continue to corresponding criteria  
   b. Juvenile idiopathic arthritis (JIA), continue to corresponding criteria  
   c. Ankylosing spondylitis (AS)/Non-radiographic axial spondyloarthritis, continue to corresponding criteria  
   d. Psoriatic arthritis (PsA), continue to corresponding criteria  
   e. Crohn’s disease, continue to corresponding criteria  
   f. Ulcerative colitis, continue to corresponding criteria  
   g. Plaque psoriasis (Ps), continue to corresponding criteria  
   h. Uveitis, continue to corresponding criteria  
   i. Other indication, continue to corresponding criteria  

Rheumatoid Arthritis

1. Is the diagnosis of rheumatoid arthritis confirmed by ACR/EULAR classification criteria AND has the diagnosis has been documented for greater for 6 months? (Provide supporting documentation)
   a. If yes, continue to #2  
   b. If no, clinical review required  

2. Does the member have moderate to severe active rheumatoid arthritis (RA) confirmed by one of the tests below despite the current RA management regimen? (Provide supporting documentation)  
   - Patient Activity Scale (PAS) or PASII of 3.7 or higher  
   - Routine Assessment of Patient Index Data 3 (RAPID3) of 2.0 or higher  
   - Clinical Disease Activity Index (CDAI) of 10 or higher  
   - Disease Activity Score (DAS) 28 erythrocyte sedimentation rate (ESR) of 3.2 or higher  
   - Simplified Disease Activity Index (SDAI) of 11 or higher  
   a. If yes, continue to #3  
   b. If no, clinical review required  

3. Did the member have an inadequate response to a 12 week trial of methotrexate? (Provide supporting documentation)
   a. If yes, continue to #7  
   b. If no, continue to #4  

4. Does the member have a contraindication or history of intolerance to methotrexate? (Note: 1. Alcohol consumption is not considered a contraindication 2. Nausea to oral formulation is not considered an intolerance) (Provide supporting documentation)
<table>
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<th>Step</th>
<th>Description</th>
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| 5.   | Did the member have an inadequate response to a 12 week trial with one of the following disease-modifying antirheumatic drugs: leflunomide (Arava), sulfasalazine (Azulfidine), hydroxychloroquine (Plaquenil)? (Provide supporting documentation)  
   a. If yes, continue to #7  
   b. If no, continue to #6 |
| 6.   | Does the member have a contraindication or history of intolerance to ALL of the following: leflunomide (Arava), sulfasalazine (Azulfidine), AND hydroxychloroquine (Plaquenil)? (Provide supporting documentation)  
   a. If yes, continue to #7  
   b. If no, clinical review required |
| 7.   | Is the request for Humira (adalimumab), Enbrel (etanercept), or Cimzia (certolizumab pegol)?  
   a. If yes, continue to #9  
   b. If no, continue to #8 |
| 8.   | Does the member have documentation of an inadequate response, intolerance, or contraindication to Humira (adalimumab), Enbrel (etanercept), or Cimzia (certolizumab pegol)? (Provide supporting documentation)  
   a. If yes, continue to #9  
   b. If no, clinical review required |
| 9.   | Is the requested treatment dose appropriate?  
   a. If yes, continue to #10  
   b. If no, clinical review required |
| 10.  | Is the medication being prescribed by or in consultation with a rheumatologist?  
   a. If yes, approve 6 months  
   b. If no, clinical review required |

**Juvenile Idiopathic Arthritis (JIA/pJIA)**

1. Does the member have moderate to severe active polyarticular JIA defined as greater or equal to 5 swollen joints and at least 3 joins with limitation in motion? (Provide documentation of affected joints and current and prior treatment regimen)  
   a. If yes, continue to #2
b. If no, clinical review required

2. Did the member have an inadequate response to a 12 week trial of methotrexate? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, continue to #3

3. Does the member have a contraindication or history of intolerance to methotrexate? (Note: 1. Alcohol consumption is not considered a contraindication. 2. Nausea to oral formulation is not considered an intolerance) (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Did the member have an inadequate response or documented intolerance to a 12 week trial of leflunomide (Arava)? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, continue to #5

5. Does the member have a contraindication or history of intolerance to leflunomide (Arava)? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the request for Humira (adalimumab), or Enbrel (etanercept)?
   a. If yes, continue to #8
   b. If no, continue to #7

7. Does the member have documentation of an inadequate response, intolerance, or contraindication to Humira (adalimumab) or Enbrel (etanercept)? (Provide supporting documentation)
   a. If yes, continue to #8
   b. If no, clinical review required

8. Is the requested treatment dose appropriate?
   a. If yes, continue to #9
   b. If no, clinical review required

9. Is the medication being prescribed by or in consultation with a rheumatologist?
   a. If yes, approve for 6 months
b. If no, clinical review required

**Ankylosing Spondylitis (AS), Non-radiographic axial spondyloarthritis**

1. **Does the member currently have active ankylosing spondylosis despite current treatment regimen?**
   (Defined as: 1. Bath ankylosing spondylitis disease activity index (BASDAI) greater or equal to 4 OR Ankylosing Spondylitis Disease Activity Score (ASDAS) greater or equal to 2.1 AND 2. Elevated CRP or positive MRI or Radiographic sacroiliitis) (Provide supporting documentation)
   
   a. If yes, continue to #2  
   b. If no, clinical review required

2. **Did the member have an inadequate response or intolerance to TWO separate 4 week trials of prescription strength oral nonsteroidal anti-inflammatory drugs (NSAIDs)?** (Provide supporting documentation)
   
   a. If yes, continue to #3  
   b. If no, clinical review required

3. **Does the member have a contraindication to oral NSAIDs?** (Provide supporting documentation)
   
   a. If yes, continue to #4  
   b. If no, clinical review required

4. **Does the member have isolated sacroiliitis, or enthesitis disease?** (Provide supporting documentation)
   
   a. If yes, continue to #5  
   b. If no, continue to #7

5. **Did the member have an inadequate response to a parenteral glucocorticoid injection?** (Provide supporting documentation)
   
   a. If yes, continue to #9  
   b. If no, continue to #6

6. **Does the member have a contraindication to a parenteral glucocorticoid injection?** (Provide supporting documentation)
   
   a. If yes, continue to #9  
   b. If no, clinical review required

7. **Did the member have an inadequate response to a 12 week trial with sulfasalazine (Azulfidine)?** (Provide supporting documentation)
   
   a. If yes, continue to #9
b. If no, continue to #8

8. Does the member have a contraindication or history of intolerance to sulfasalazine (Azulfidine)? (Provide supporting documentation)
   a. If yes, continue to #10
   b. If no, continue to #9

9. Does the member have active axial disease? (Provide supporting documentation)
   a. If yes, continue to #10
   b. If no, clinical review required

10. Is the request for Humira (adalimumab), Enbrel (etanercept), or Cimzia (certolizumab pegol)?
    a. If yes, continue to #12
    b. If no, continue to #11

11. Does the member have documentation of an inadequate response, intolerance, or contraindication to TWO of the following: Humira (adalimumab), Enbrel (etanercept), or Cimzia (certolizumab pegol)? (Provide supporting documentation)
    a. If yes, continue to #12
    b. If no, clinical review required

12. Is the requested treatment dose appropriate?
    a. If yes, continue to #13
    b. If no, clinical review required

13. Is the medication being prescribed by or in consultation with a rheumatologist?
    a. If yes, approve for 6 months
    b. If no, clinical review required

Psoriatic Arthritis (PsA)

1. Does the member currently have active psoriatic arthritis (PsA) defined as greater or equal to 3 swollen joints AND greater or equal to 3 tender or painful joints despite current treatment regimen? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member have predominantly axial disease or severe enthesitis? (Provide supporting documentation)  
   a. If yes, continue to #3  
   b. If no, continue to #5  

3. Did the member have an inadequate response or intolerance to TWO separate 4 week trials of oral prescription strength Nonsteroidal anti-inflammatory drugs (NSAIDs) OR a prescription strength oral NSAID and parenteral glucocorticoid injection? (Provide supporting documentation)  
   a. If yes, continue to #9  
   b. If no, continue to #4  

4. Does the member have a contraindication to oral NSAIDs? (Provide supporting documentation)  
   a. If yes, continue to #9  
   b. If no, clinical review required  

5. Did the member have an inadequate response to a 12 week trial of methotrexate? (Provide supporting documentation)  
   a. If yes, continue to #9  
   b. If no, continue to #6  

6. Does the member have a contraindication or history of intolerance to methotrexate? (Note: 1. Alcohol consumption is not considered a contraindication. 2. Nausea to oral formulation is not considered an intolerance) (Provide supporting documentation)  
   a. If yes, continue to #7  
   b. If no, clinical review required  

7. Did the member have an inadequate response to a 12 week trial with one of the following: leflunomide (Arava) OR sulfasalazine (Azulfidine)? (Provide supporting documentation)  
   a. If yes, continue to #9  
   b. If no, continue to #8  

8. Does the member have a contraindication or history of intolerance to ALL of the following: leflunomide (Arava) AND sulfasalazine (Azulfidine)? (Provide supporting documentation)  
   a. If yes, continue to #9  
   b. If no, clinical review required  

9. Is the request for Humira (adalimumab), Enbrel (etanercept), or Cimzia (certolizumab pegol)?  
   a. If yes, continue to #13
b. If no, continue to #10

10. Does the member have documentation of an inadequate response, intolerance, or contraindication to TWO of the following: Humira (adalimumab), Enbrel (etanercept), or Cimzia (certolizumab pegol)? (Provide supporting documentation)
   a. If yes, continue to #11
   b. If no, clinical review required

11. Is the request for Cosentyx (secukinumab)?
   a. If yes, continue to #13
   b. If no, continue to #12

12. Did the member have an inadequate response to 12 week trials with Cosentyx (secukinumab)? (Provide supporting documentation)
   a. If yes, continue to #13
   b. If no, clinical review required

13. Is the requested treatment dose appropriate?
   a. If yes, continue to #14
   b. If no, clinical review required

14. Is the medication being prescribed by or in consultation with a rheumatologist or dermatologist?
   a. If yes, approve for 6 months
   b. If no, clinical review required

Crohn’s Disease (CD)

1. Does the member currently have active Crohn’s Disease despite the current treatment regimen? (Defined as Crohn’s Disease Activity Index (CDAI) greater than 220, record CDAI) (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Did the member have an inadequate response to TWO separate 12 week trials with TWO of the following oral agents: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate, mesalamine? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, continue to #3
3. Does the member have a contraindication or history of intolerance to ALL of the following oral agents: 6-mercaptopurine, azathioprine, corticosteroids, methotrexate, mesalamine, sulfasalazine? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the requested treatment dose appropriate?
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the medication being prescribed by or in consultation with a gastroenterologist?
   a. If yes, approve for 6 months
   b. If no, clinical review required

Ulcerative Colitis (UC)

1. Does the member currently have active Ulcerative Colitis despite the current treatment regimen? (Diagnosis confirmed by endoscopy, colonoscopy, or sigmoidoscopy with Mayo score of greater than 6) (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no clinical review required

2. Did the member have an inadequate response to TWO separate 12 week trials with TWO of the following oral agents: aminosalicylates (sulfasalazine, mesalamine, balsalazide), corticosteroids, azathioprine, 6-mercaptopurine? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, continue to #3

3. Does the member have a contraindication or history of intolerance to ALL of the following oral agents: 6-mercaptopurine, azathioprine, corticosteroids, methotrexate, mesalamine, sulfasalazine? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the requested treatment dose appropriate?
   a. If yes, continue to #5
   b. If no, clinical review required
5. Is the medication being prescribed by or in consultation with a gastroenterologist?
   a. If yes, approve for 6 months
   b. If no, clinical review required

Plaque Psoriasis (Ps)

1. Does the member currently have moderate to severe chronic plaque psoriasis defined as having functional impairment (e.g. inability to use hands or feet or activities of daily living, or significant facial involvement preventing normal social interaction) AND one or more of the following: 1. At least 10% body surface area involvement AND/OR 2. Hand, foot or mucous membrane involvement? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Did the member have an inadequate response to a 12 week trial with **TWO** of the following systemic therapies: methotrexate, cyclosporine, phototherapy? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the request for Humira (adalimumab), Enbrel (etanercept), or Cimzia (certolizumab pegol)?
   a. If yes, continue to #7
   b. If no, continue to #4

4. Does the member have documentation of an inadequate response, intolerance, or contraindication to Humira (adalimumab), Enbrel (etanercept), or Cimzia (certolizumab pegol)? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no clinical review required

5. Is the request for Cosentyx (secukinumab)?
   a. If yes, continue to #7
   b. If no, continue to #6

6. Did the member have an inadequate response to 12 week trials with Cosentyx (secukinumab)? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required
7. Is the requested treatment dose appropriate?
   a. If yes, continue to #8
   b. If no, clinical review required

8. Is the treatment being prescribed by or in consultation with a dermatologist?
   a. If yes, approve for 6 months
   b. If no, clinical review required

Uveitis

1. Does the member currently have non-infectious intermediate uveitis, posterior uveitis, or panuveitis? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Did the member have an inadequate response to TWO separate 12 week trials with two of the following oral agents: cyclosporine, tacrolimus, azathioprine, methotrexate, mycophenolate? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, continue to #3

3. Does the member have a contraindication or history of intolerance to ALL of the following oral agents: cyclosporine, tacrolimus, azathioprine, methotrexate, mycophenolate? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the requested treatment dose appropriate?
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the medication being prescribed by or in consultation with an ophthalmologist or rheumatologist?
   a. If yes, approve for 6 months
   b. If no, clinical review required
Other Indications

1. Is the requested use supported by major compendia? (Examples: Micromedex, Clinical Pharmacology, etc.) (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member tried and had an inadequate response to OR does the member have a contraindication to ALL standard treatment options for the requested indication? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the requested treatment dose appropriate?
   a. If yes, continue to #4
   b. If no, clinical review required

4. Will the requested medication be used with other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Orencia, Taltz, Cosentyx, Otezla, etc.)
   a. If yes, clinical review required
   b. If no, continue to #5

5. Is the treatment being prescribed by or in consultation with an appropriate specialist?
   a. If yes, approve for 6 months
   b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication FDA approved or supported by major compendia? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Were updated chart notes (dated within 1 year) provided with documentation of significant clinical response to therapy? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the requested treatment dose appropriate?
   a. If yes, continue to #4
   b. If no, clinical review required

4. Will the requested medication be used with other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Ocrecia, Taltz, Cosentyx, Otezla, etc.)
   a. If yes, clinical review required
   b. If no, continue to #5

5. Is the treatment being prescribed by or in consultation with an appropriate specialist?
   a. If yes, approve for 12 months reauthorization
   b. If no, clinical review required

Note:
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:


Last Reviewed: 11/26/19
Effective Date: 1/1/19


**Victoza (liraglutide)**  
**Prior Authorization Guidelines**

### Affected Medication(s)
- Victoza subcutaneous injection

### FDA Approved Indication(s)
- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease
- Note: Victoza is not a substitute for insulin and should not be used in patients with type 1 DM or for the treatment of ketoacidosis. Concurrent use of Victoza and prandial insulin has not been studied.

### Dosing
- 1.2 mg to 1.8 mg given as subcutaneous injection once-daily

### Initial Authorization Criteria

1. **Is the diagnosis provided and covered by Oregon Health Plan (OHP)?** (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, deny. Not funded by OHP

2. **Is the request for renewal of a previously approved Victoza (liraglutide) prior authorization with the same indication?**
   - a. If yes, continue to **Reauthorization**
   - b. If no, continue to #3

3. **Is Victoza (liraglutide) being requested for an FDA approved indication?** (Provide supporting documentation)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. **Was a baseline HbA1c level provided?** (Provide supporting documentation)
   - a. If yes, continue to #5
   - b. If no, clinical review required
5. Did the member have an inadequate response to metformin? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, continue to #6

6. Did the member have an intolerance to metformin despite proper dose titration OR a contraindication to metformin? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Did the member have an inadequate response or contraindication to one of the following Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors- Invokana, Steglatro, Jardiance, or Farxiga? (Provide supporting documentation)
   a. If yes, approve for 6 months
   b. If no, clinical review required

### Reauthorization Criteria

1. Is the documented indication FDA approved or supported by major compendia? (Verify dosing with package insert) (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Were updated HbA1c and chart notes (within 1 year) provided with documentation of significant clinical response? (Provide supporting documentation)
   a. If yes, approve for 12 months
   b. If no, clinical review required

**Note:**

Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

**References:**

Vigabatrin
Prior Authorization Guidelines

Affected Medication(s)

- Vigabatrin oral packet
- Vigabatrin oral tablet

FDA Approved Indication(s)

- Adjunctive therapy in patients 10 years of age or older with refractory complex partial seizures who had an inadequate response to several alternative treatments (Note: Vigabatrin is not indicated as a first line agent)
- As monotherapy in infants 1 month to 2 years of age with infantile spasms for whom the potential benefits outweigh the potential risk of vision loss

Dosing

- Refractory Complex Partial Seizures
  - Pediatric: 2000 mg per day; dose patients weighing more than 60 kg with adult dosing
  - Adults: 3000 mg per day
- Infantile Spasms: maximum daily dose of 150 mg/kg

Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, deny. Not funded by OHP

2. Is the request for renewal of a previously approved vigabatrin prior authorization with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #3

3. What is the diagnosis that vigabatrin is being requested for?
   a. Refractory complex partial seizures, continue to corresponding criteria
   b. Infantile spasm, continue to corresponding criteria
   c. Other indication, clinical review required
Refractory Complex Partial Seizures

1. Did the member have inadequate seizure control with at least TWO of the following anticonvulsants in the past: felbamate, lamotrigine, levetiracetam, oxcarbazepine, gabapentin, topiramate, tiagabine, zonisamide, lacosamide? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does documentation indicate potential benefits from treatment outweigh the risk of vision loss provided?
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is documentation of a baseline vision assessment provided?
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the tablet formulation being requested?
   a. If yes, continue to #5
   b. If no, continue to #6

5. Does the member have a contraindication to packet formulation? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the medication being prescribed by or in consultation with a neurologist who is certified with the SHARE program?
   a. If yes, approve for 4 months
   b. If no, clinical review required

Infantile Spasm

1. Does the documentation indicate potential benefits from treatment outweigh the risk of vision loss provided? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the tablet formulation being requested?
   a. If yes, continue to #3
   b. If no, continue to #4

3. Does the member have a contraindication to packet formulation? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the medication being prescribed by or in consultation with a neurologist who is certified with the SHARE program?
   a. If yes, approve for 2 months
   b. If no, clinical review required

Reauthorization Criteria

1. Is Sabril being prescribed for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Were updated chart notes (within 1 year) with documentation of routine vision assessment and significant clinical response to prior therapy received? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with a neurologist who is certified with the SHARE program?
   a. If yes, approve for 12 months
   b. If no, clinical review required

Note:
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References:


Vimpat (lacosamide)
Prior Authorization Guidelines

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Vimpat oral tablet</td>
</tr>
<tr>
<td>• Vimpat oral solution</td>
</tr>
<tr>
<td>• Vimpat intravenous solution</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FDA Approved Indication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• As treatment of partial-onset seizures in patients 4 years of age and older</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 4 to 8 mg/kg per day up to 200 mg per day</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial Authorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)</td>
</tr>
<tr>
<td>a. If yes, continue to #2</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td>2. Is the request for renewal of a previously approved Vimpat (lacosamide) prior authorization with the same indication?</td>
</tr>
<tr>
<td>a. If yes, continue to Reauthorization</td>
</tr>
<tr>
<td>b. If no, continue to #3</td>
</tr>
<tr>
<td>3. Is Vimpat (lacosamide) being requested for an FDA approved indication? (Provide supporting documentation)</td>
</tr>
<tr>
<td>a. If yes, continue to #4</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td>4. Has the member had a trial of at least TWO of the following anticonvulsants but continued to have inadequate seizure control- felbamate, lamotrigine, levetiracetam, oxcarbazepine, gabapentin, topiramate, tiagabine, zonisamide? (Document all therapies tried) (Provide supporting documentation)</td>
</tr>
<tr>
<td>a. If yes, continue to #5</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
</tbody>
</table>
5. Is the treatment being prescribed by or in consultation with a neurologist?
   a. If yes, approve for 12 months reauthorization
   b. If no, clinical review required

Reauthorization Criteria

1. Is Vimpat being prescribed for an FDA approved indication? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Were updated chart notes (within 1 year) with documentation of significant clinical response to prior therapy received? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the treatment being prescribed by or in consultation with a neurologist?
   a. If yes, approve for 12 months reauthorization
   b. If no, clinical review required

Note:
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References:


# Xifaxan (rifaximin)

## Prior Authorization Guidelines

### Affected Medication(s)

- Xifaxan oral tablet

### FDA Approved Indication(s)

- **Traveler's Diarrhea (TD):** Treatment of traveler's diarrhea caused by noninvasive strains of *Escherichia coli* in adults and pediatric patients 12 years of age and older (not-funded)
- **Hepatic Encephalopathy (HE):** For reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults
- **Irritable Bowel Syndrome with diarrhea (IBS-D):** Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults (not-funded)

### Dosing

- **TD:** 200 mg three times daily for 3 days
- **HE:** 550 mg twice daily
- **IBS-D:** 550 mg by mouth three times daily for 14 days

### Initial Authorization Criteria

1. Is the diagnosis provided and covered by Oregon Health Plan (OHP)? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, deny. Not funded by OHP

2. Is the request for renewal of a previously approved Xifaxan (rifaximin) prior authorization for treatment of hepatic encephalopathy (HE)?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #3

3. What is the diagnosis that Xifaxan (rifaximin) is being requested for?
   - a. Traveler's Diarrhea, clinical review required
   - b. Hepatic Encephalopathy, continue to corresponding criteria
   - c. Irritable Bowel Syndrome with Diarrhea. Not funded by OHP
   - d. Other indication, continue to corresponding criteria
Hepatic Encephalopathy

1. Is the member 18 years of age or older?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a trial with insufficient response to lactulose in the past 30 days up to the maximum indicated dose? (Insufficient response defined as continued altered mental status) (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, continue to #4

3. Will the member continue to take lactulose concurrently with Xifaxan (rifaximin)? (Provide supporting documentation)
   a. If yes, approve 6 months
   b. If no, clinical review required

4. Does the member have an intolerance or contraindication to lactulose? (Note: Dose dependent GI discomfort and/or diarrhea is not considered as intolerance) (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have altered mental status? (Provide supporting documentation)
   a. If yes, approve 6 months
   b. If no, clinical review required

Other Indications

1. Is the requested use supported by major compendia? (Examples: Micromedex, Clinical Pharmacology, etc.) (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member tried and had an inadequate response OR does the member have a contraindication to ALL standard treatment options of the required indication? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the requested treatment dose and treatment duration appropriate? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the treatment being prescribed or in consultation with an appropriate specialist?
   a. If yes, approve up to 6 months (based on appropriate treatment duration)
   b. If no, clinical review required

Reauthorization Criteria

1. Is Xifaxan (rifaximin) being used concurrently with lactulose unless a contraindication or intolerance is present? (Note: Dose dependent GI discomfort and/or diarrhea is not considered as intolerance) (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member responding positively to therapy as defined by a decrease in symptoms? (Provide supporting documentation)
   a. If yes, approve 6 months
   b. If no clinical review required

Note:
Medication prior authorization guidelines are developed by a team of health care professionals based on standards of practice at the time of approval. Guidelines are used as a basis for making coverage decisions and do not serve as medical advice. Coverage of medications is subject to plan provisions. Additional coverage restrictions not listed in the guidelines may apply.

References:

