Affected Medication(s)

- Grastek sublingual tablet
- Odactra sublingual tablet
- Oralair sublingual tablet
- Ragwitek sublingual tablet

FDA Approved Indication(s)

- **Grastek**: As an immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens for patient between 5 and 65 years of age
- **Odactra**: As an immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts for adult patient between 18 and 65 years of age
- **Oralair**: As an immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for any of the five grass species contained in this product for patient between 10 and 65 years of age
- **Ragwitek**: As an immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen for adult patient between 18 and 65 years of age

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Authorization Criteria

1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member remain symptomatic despite treatment with a nasal steroid AND oral antihistamine at the maximum indicated doses? (Provide supporting documentation of relevant past/current medication history and symptom history)
   a. If yes, continue to #3
   b. If no, clinical review required
3. For Grastek, Oralair, and Ragwitek: Will the treatment begin prior to the start of allergy season and continue throughout the allergy season? (12 weeks prior for Grastek or Ragwitek, 16 weeks prior for Oralair)
   a. If yes, continue to #4
   b. If no, clinical review required
   c. If not applicable, continue to #4
4. Does the member have a positive skin test or in vitro testing for pollen specific IgE antibodies to the corresponding allergen listed below? (Provide relevant test results for review)
   - Grastek: Timothy grass or cross-reactive grass
   - Odactra: *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites
   - Oralair: Sweet vernal, Orchard, perennial Rye, Timothy, or Kentucky blue grass
   - Ragwitek: Short Ragweed
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have any of the following contraindications to the requested treatment?
   - Severe, unstable, or uncontrolled asthma
   - History of any severe systemic allergic reaction or severe local reaction after taking any sublingual allergen immunotherapy
   - History of eosinophilic esophagitis
   - Hypersensitivity to any of the inactive ingredients
   a. If yes, clinical review required
   b. If no, continue to #6

6. Is the treatment being prescribed by, or in consult with an allergist, immunologist, or otolaryngologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

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

# Amicar® (aminocaproic acid)
## Prior Authorization Guidelines

### Affected Medication(s)
- Amicar oral solution
- Amicar oral tablet

### FDA Approved Indication(s)
- Enhancing hemostasis when fibrinolysis contributes to bleeding

### Dosing
- 5 g administered during the first hour of treatment, followed by a continuing rate of 1 to 1.25 g per hour, continued for about 8 hours or until the bleeding situation has been controlled

### Authorization Criteria
1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, clinical review required
2. Does the member have a trial with inadequate response, intolerance, or contraindication to tranexamic acid? (Provide documentation of trial with inadequate response, intolerance, or contraindication)
   - a. If yes, approve for 1 month unless otherwise specified
   - b. If no, clinical review required

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### References:
Ampyra® (dalampridine)
Prior Authorization Guidelines

Affected Medication(s)
- Ampyra oral tablet

FDA Approved Indication(s)
- To improve walking in adult patients with multiple sclerosis (MS)

Dosing
- Maximum dose of 10mg twice daily

Initial Authorization Criteria
1. Is the request for continuation of Ampyra (dalfampridine) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is the member’s walking ability impacted by multiple sclerosis and is clinical documentation with baseline walking ability received? (Provide documentation of baseline walking ability)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is Ampyra (dalfampridine) being prescribed by or in consultation with a neurologist?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is clinical documentation confirming responsiveness to therapy provided? (Provide documentation of increased walking distance, improved leg/limb strength, and/or improvement in activities of daily living)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is Ampyra (dalfampridine) being prescribed by or in consultation with a neurologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required
**Note:**

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**References:**


### Affected Medication(s)
- Anadrol-50 oral tablet

### FDA Approved Indication(s)
- For the treatment of anemias caused by deficient red cell production. Acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs often respond

### Dosing
- 1-5 mg/kg per day

### Initial Authorization Criteria

1. Is the request for continuation of Anadrol-50 (oxymetholone) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

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

3. Is Anadrol-50 (oxymetholone) being requested for use to treat cachexia associated with HIV/AIDS?
   - a. If yes, continue to #4
   - b. If no, continue to #5

4. Is the member currently adherent to an antiretroviral therapy? (Provide documentation of antiretroviral therapy regimen)
   - a. If yes, continue to #8
   - b. If no, clinical review required

5. Is Anadrol-50 (oxymetholone) being requested for anemia caused by deficient red blood cell production?
   - a. If yes, continue to #6
   - b. If no, continue to #7

6. Does the member have a trial with insufficient response, intolerance, or contraindication to at least 2 alternative standard treatments for anemia? (Examples include erythropoiesis-stimulating agents, immunosuppressants, etc.). (Provide documentation of insufficient response, intolerance, or contraindication)
   - a. If yes, continue to #8
   - b. If no, clinical review required

7. Is Anadrol-50 (oxymetholone) being requested for an alternative indication that is supported by major compendia? (Provide documentation supporting indication and dosing)
8. Does the member have any of the following contraindications to therapy with Anadrol-50 (oxymetholone)?

- Carcinoma of the prostate or breast in males
- Carcinoma of the breast in female with hypercalcemia
- Pregnancy
- Nephrosis or the nephrotic phase of nephritis
- Severe hepatic dysfunction
- Hypersensitivity to the drug

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

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**Reauthorization Criteria**

1. Is the request for an FDA approved or a compendia supported indication? (Provide documentation of diagnosis)

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

2. Does the member have a positive clinical response to therapy? (e.g. increased hemoglobin or reticulocyte count or reduction/elimination for need of blood transfusions in anemia and/or a decrease in cachexia associated with HIV/AIDS)

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

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**References:**

Affected Medication(s)

- Apokyn subcutaneous solution

FDA Approved Indication(s)

- For the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced Parkinson's disease

Dosing

- Initially 0.2 ml (2 mg) titrated up to a maximum of 0.6 ml (6 mg)

Initial Authorization Criteria

1. Is the request for continuation of Apokyn (apomorphine hydrochloride) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have significant hypomobility or "off" episodes that last at least 2 hours? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member on a maximally tolerated dose of levodopa AND one of the following? (Provide relevant medication history)
   - Selegiline
   - Ropinirole
   - Pramipexole
   - Entacapone
   - Rasagiline
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have any of the following contraindications to Apokyn:
   - Concurrent use with 5HT₃ antagonist agents including antiemetics and alosetron
   - Hypersensitivity to apomorphine, its excipients or sodium metabisulfite
   a. If yes, clinical review required
   b. If no, continue to #6

6. Is the treatment being prescribed by, or in consultation with, a neurologist?
   a. If yes, approve for 12 months unless otherwise specified

Last Reviewed: 10/17/18
Effective Date: 1/1/19
### Reauthorization Criteria

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

2. Is the member demonstrating positive clinical response to therapy defined by a decrease in frequency of hypomobility or “off” episodes? (Provide supporting documentation)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

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**References:**

### 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 request for continuation of Aranesp (darbepoetin alfa) therapy?**
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

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

4. **Does the member have a serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%? (Provide labs for review)**
   a. If yes, continue to #5
   b. If no, clinical review required

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

7. **Which indication is Aranesp (darbepoetin alfa) being requested for? (Record submitted diagnosis and review all criteria based on the submitted diagnosis)**
   a. Anemia secondary to myelodysplastic syndrome (MDS), continue to corresponding criteria

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Last Reviewed: 10/17/18
Effective Date: 1/1/19
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 unless otherwise specified
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 member’s endogenous serum erythropoietin level ≤ 500 mUnits/mL? (Provide lab for review)
   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 member’s endogenous serum erythropoietin level < 500 mUnits/mL? (Provide lab for review)
   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?
   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 documentation of treatment plan)
   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 documentation of diagnosis)
   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 all prior treatment history, contraindication if appropriate, and treatment plan)
### Reauthorization Criteria

1. **Was the last dose of Aranesp (darbepoetin alfa) less than 60 days ago?** (Provide date of last dose)
   - 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?** (Provide updated clinical documentation for review)
   - 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)
   - 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)?** (Provide updated lab result for review)
   - 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 lab result for review)
   - 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?**
   - 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 clinical 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 myelosuppressive 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 |

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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.


## Affected Medication(s)
- Arcalyst powder for reconstitution for subcutaneous solution

## FDA Approved Indication(s)
- For treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older

## Dosing
- **Adults 18 years and older:**
  - Loading dose: 320 mg subcutaneously
  - Maintenance: 160 mg subcutaneously once weekly
- **Pediatrics 12-17 years old:**
  - Loading dose: 4.4 mg/kg (max of 320 mg) subcutaneously
  - Maintenance: 2.2 mg/kg (max of 160 mg) subcutaneously once weekly

## Initial Authorization Criteria
1. Is the request for continuation of Arcalyst (rilonacept) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   - a. If yes, continue to #3
   - b. If no, clinical review required
3. Is the member 12 years of age or older?
   - a. If yes, continue to #4
   - b. If no, clinical review required
4. Will Arcalyst (rilonacept) be used with other biologic agent(s)? (Examples: Kineret, Ilaris, Actemra)
   - a. If yes, clinical review required
   - b. If no, continue to #5
5. Is the treatment being prescribed by or in consultation with a rheumatologist?
   - a. If yes, approve for 6 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 documentation of diagnosis)
   - 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, continue to #3
   b. If no, clinical review required

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

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References:
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 request for continuation of Banzel (rufinamide) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2
2. Is the request for use to treat an FDA-approved indication? (Provide documentation of diagnosis)
   - a. If yes, continue to #3
   - b. If no, clinical review required
3. Has the member previously tried at least ONE of the following therapies – valproate or lamotrigine?
   - a. If yes, continue to #5
   - b. If no, continue to #4
4. Does the member have a history of intolerance or contraindication to valproate AND lamotrigine? (Provide documentation of intolerance and/or contraindication)
   - a. If yes, continue to #5
   - b. If no, clinical review required
5. Does the member have familial short QT syndrome?
   - a. If yes, clinical review required
   - b. If no, continue to #6
6. Is the treatment being prescribed by or in consultation with a neurologist?
   - a. If yes, approve for 12 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 documentation of diagnosis)
   - 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 at least 20% reduction in seizure frequency? (Provide documentation of decreased seizure frequency)
   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 unless otherwise specified
   b. If no, clinical review required

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References:
<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
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<tbody>
<tr>
<td>• Benlysta subcutaneous solution</td>
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<thead>
<tr>
<th>FDA Approved Indication(s)</th>
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</thead>
<tbody>
<tr>
<td>• Treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy</td>
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<tr>
<th>Dosing</th>
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<tr>
<td>• 200 mg subcutaneously once weekly</td>
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<thead>
<tr>
<th>Initial Authorization Criteria</th>
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<tbody>
<tr>
<td>1. Is the request for continuation of Benlysta (belimumab) therapy?</td>
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<tr>
<td>a. If yes, continue to Reauthorization</td>
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<tr>
<td>b. If no, continue to #2</td>
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<tr>
<td>2. Is the member 18 years or older with a positive autoantibody test? (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA) (Provide test result for review)</td>
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<tr>
<td>a. If yes, continue to #3</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
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<tr>
<td>3. Has the member failed to respond adequately to at least TWO (2) standard therapies (anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives (excluding intravenous cyclophosphamide))? (Provide documentation of treatment history)</td>
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<tr>
<td>a. If yes, continue to #4</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
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<tr>
<td>4. Does the member have one of the following? (Provide assessment score for review)</td>
</tr>
<tr>
<td>• Safety of Estrogen in Lupus National Assessment – Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of 6-12</td>
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<tr>
<td>• British Isles Lupus Assessment Group (BILAG) A organ domain score ≥1</td>
</tr>
<tr>
<td>• BILAG B organ domain score ≥2;</td>
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<tr>
<td>a. If yes, continue to #5</td>
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<td>b. If no, clinical review required</td>
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<tr>
<td>5. Does the member have an active infection?</td>
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<tr>
<td>a. If yes, clinical review required</td>
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<tr>
<td>b. If no, continue to #6</td>
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<tr>
<td>6. Has the member received a live vaccine within 30 days before starting or concurrently with Benlysta?</td>
</tr>
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<td>a. If yes, clinical review required</td>
</tr>
</tbody>
</table>
b. If no, continue to #7

7. Does the member have any of the following exclusion criteria?
   - Severe active central nervous system lupus
   - Severe active lupus nephritis
   - Individuals who are on other biologics or IV cyclophosphamide

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

8. Is Benlysta (belimumab) being prescribed by or in consultation with a rheumatologist or specialist experienced in treatment of SLE?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

### Reauthorization Criteria

1. Does member continue to meet initial authorization criteria as outlined above?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Were updated chart notes (within 1 year) provided with documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline? (Provide updated assessment score for review)
   - Improvement in the SELENA-SLEDAI score of ≥4 points; OR
   - No new BILAG-A organ domain score or 2 new BILAG-B organ domain scores; OR
   - No worsening (<0.30-point increase) in Physician’s Global Assessment (PGA) score; OR
   - Seroconverted (negative) or had a 20% reduction in autoantibody level;

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

3. Is there documentation of an absence of unacceptable toxicity from the medication? (Examples of unacceptable toxicity include the following: depression, suicidal thoughts, serious infections, signs or symptoms of progressive multifocal leukoencephalopathy (PML), malignancy, severe hypersensitivity reaction, etc.)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is Benlysta (belimumab) being prescribed by or in consultation with a rheumatologist or specialist experienced in treatment of SLE?
   a. If yes, approve for 12 months reauthorization 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:

# Bethkis®, Tobi Podhaler® (tobramycin) Prior Authorization Guidelines

## Affected Medication(s)
- Bethkis inhalation solution
- Tobi Podhaler inhalation capsule

## FDA Approved Indication(s)
- For the management of cystic fibrosis patients with *Pseudomonas aeruginosa*

## Dosing
- **Bethkis**
  - For adults and children 6 years of age and older: Inhale 1 ampule (300mg/4ml) twice daily via nebulization in cycles of 28 days on drug, 28 days off of drug
- **Tobi Podhaler**
  - For adult and children 6 years of age and older: Inhale contents of four 28 mg capsules twice daily via podhaler device in cycles of 28 days on drug, 28 days off of drug

## Initial Authorization Criteria

1. Is the request for continuation of Bethkis or Tobi Podhaler therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

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

3. Does the member have a diagnosis of cystic fibrosis and a positive culture demonstrating infection with *Pseudomonas aeruginosa*? (Provide supporting documentation of diagnosis and positive culture for *Pseudomonas aeruginosa*)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. For Bethkis: Does the member have baseline FEV1 greater than or equal to 40%? (Provide baseline FEV1 for review)
   - For Tobi Podhaler: Does the member have baseline FEV1 greater than or equal to 25%? (Provide baseline FEV1 for review)
   - a. If yes, continue to #5
   - b. If no, clinical review required

5. Has the member had a medical rationale for avoiding therapy with, generic tobramycin inhaled solution? (Provide documentation of medical rationale for avoidance)
   - a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a positive response to therapy as defined by stability in their disease state? (Provide supporting documentation for review)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:
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References:
Buphenyl® (sodium phenylbutyrate tablet)
Prior Authorization Guidelines

Affected Medication(s)

- Buphenyl oral powder
- Buphenyl oral tablet

FDA Approved Indication(s)

- Adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS)
  - Indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life)
  - Indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemnic encephalopathy

Dosing

- Usual total daily dose is 450–600 mg/kg/day in patients weighing less than 20 kg, or 9.9–13.0 g/m²/day in larger patients
- Total daily dose should be divided equally between each meal (3-6 times per day)

Initial Authorization Criteria

1. Is the request for continuation of Buphenyl (sodium phenylbutyrate) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is the diagnosis confirmed by blood, enzyme, or genetic testing? (Provide lab result for review)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the baseline plasma ammonia level provided? (Provide lab result for review)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the member adherent to a protein restrictive diet? (Provide documentation of restrictive diet)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is documentation of trial or rationale for avoiding generic sodium phenylbutyrate received? (Provide supporting documentation)
   a. If yes, continue to #7
### Reauthorization Criteria

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

2. Is the member adherent to a protein restrictive diet? (Provide documentation of restrictive diet)
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. Does the member show a positive clinical response to therapy as defined by normalized plasma ammonia levels? (Provide documentation of normalized plasma ammonia levels)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or 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:**

Carbaglu® (carglumic acid)
Prior Authorization Guidelines

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
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</thead>
<tbody>
<tr>
<td>• Carbaglu oral tablet</td>
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<table>
<thead>
<tr>
<th>FDA Approved Indication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adjunctive therapy in pediatric and adult patients for treatment of acute hyperammonemia due to deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS)</td>
</tr>
<tr>
<td>• Maintenance therapy in pediatric and adult patients for treatment of chronic hyperammonemia due to deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS)</td>
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<tr>
<th>Dosing</th>
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<tbody>
<tr>
<td>• Acute: 100 mg/kg to 250 mg/kg divided into 2 to 4 doses (rounded to the nearest 100 mg)</td>
</tr>
<tr>
<td>• Maintenance: 10 mg/kg to 100 mg/kg divided into 2 to 4 doses (rounded to the nearest 100 mg)</td>
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<tr>
<th>Initial Authorization Criteria</th>
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<tbody>
<tr>
<td>1. Is the request for continuation of Carbaglu (carglumic acid) therapy?</td>
</tr>
<tr>
<td>a. If yes, continue to Reauthorization</td>
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<tr>
<td>b. If no, continue to #2</td>
</tr>
<tr>
<td>2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)</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>3. Is the diagnosis of NAGS deficiency confirmed by plasma amino acid/urine orotic acid or enzyme analysis? (Provide lab report confirming diagnosis)</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. Is baseline plasma ammonia level provided? (Provide lab for review)</td>
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<tr>
<td>a. If yes, continue to #5</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td>5. Will Cargablu (carglumic acid) be used with other methods to lower plasma ammonia level? (i.e. hemodialysis, sodium phenylacetate and sodium benzoate)</td>
</tr>
<tr>
<td>a. If yes, continue to #6</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
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<tr>
<td>6. Is the member adherent to a protein restrictive diet? (Provide documentation of restrictive diet)</td>
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<tr>
<td>a. If yes, continue to #7</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
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</table>
7. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
   a. If yes, approve for 3 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member show a positive clinical response to therapy as defined be a decrease in plasma ammonia levels from baseline? (Provide documentation of current and baseline plasma ammonia levels for review)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:

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References:

**Affected Medication(s)**
- Cayston powder for inhalation solution

**FDA Approved Indication(s)**
- To improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa*

**Dosing**
- For adults and children 7 years of age and older:
  - One vial (75mg) reconstituted with 1 mL of sterile diluent administered 3 times a day for a 28 day course

**Initial Authorization Criteria**

1. Is the request for continuation of Cayston® (aztreonam) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

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

3. Does the member have cystic fibrosis and a lung infection with a positive culture demonstrating *Pseudomonas aeruginosa* infection? (Provide supporting documentation of cystic fibrosis diagnosis and positive culture for *Pseudomonas aeruginosa*)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. Does the member have baseline FEV1 greater than 25%? (Provide FEV1 for review)
   - a. If yes, continue to #5
   - b. If no, clinical review required

5. Does the member have a previous trial with inadequate response, contraindication, or intolerance to tobramycin inhaled solution? (Provide supporting documentation for review)
   - a. If yes, approve for 1 month unless otherwise specified
   - b. If no, continue to # 6

6. Does the member have a culture showing resistance to tobramycin? (Provide culture results for review)
   - a. If yes, approve for 1 month unless otherwise specified
   - b. If no, clinical review required

**Reauthorization Criteria**

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

2. Is documentation confirming improvement in respiratory symptoms provided? (Provide supporting documentation for review)
   a. If yes approve for 12 months unless otherwise specified
   b. If no, clinical review required

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References:
CGRP Antagonists
Prior Authorization Guidelines

Affected Medication(s)

- Aimovig (erenumab-aooe) subcutaneous solution
- Ajovy (fremanezumab-vfrm) subcutaneous solution
- Emgality (galcanezumab-gnlm) subcutaneous solution

FDA Approved Indication(s)

- For the preventive treatment of migraine in adults

Dosing

- Aimovig: 70 mg to 140 mg subcutaneously once monthly
- Ajovy: 225 mg subcutaneously once monthly or 675 mg subcutaneously every 3 months
- Emgality: 240 mg subcutaneously once as loading dose, then 120 mg subcutaneously once monthly

Initial Authorization Criteria

1. Is the request for continuation of therapy with the same CGRP antagonist?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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. Over a period of the last 3 months, has the member experienced 15 or more migraine headache days per month? (Provide documentation of migraine history/frequency)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Has the member had 2-month trials with inadequate responses to at least 2 alternative agents with differing mechanisms of action used for migraine prophylaxis? (Examples include antiepileptic drugs, beta-blockers, TCAs, and/or SNRIs) (Provide documentation of trial history)
   a. If yes, continue to #7
   b. If no, continue to #6

6. Does the member have contraindications to all of the following alternative agents used for migraine prophylaxis: antiepileptic drugs, beta-blockers, TCAs, and/or SNRIs? (Provide supporting documentation of contraindications)
   a. If yes, continue to #7
   b. If no, clinical review required
7. Will CGRP antagonist to be used in combination with Botox?
   a. If yes, clinical review required
   b. If no, continue to #8

8. Is clinical rationale provided for needing to avoid formulary preferred agent?
   a. If yes, continue to #9
   b. If no, clinical review required

9. Is the treatment being prescribed by, or in consultation with, a neurologist or migraine specialist?
   a. If yes, approve for 6 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 documentation of diagnosis)
   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 reduction in the frequency of migraine days per month from pre-treatment baseline?
   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 or migraine specialist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

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References:
**Chenodal® (chenodiol)**  
**Prior Authorization Guidelines**

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
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<tbody>
<tr>
<td>• Chenodal oral tablet</td>
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<tr>
<th>FDA Approved Indication(s)</th>
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<tbody>
<tr>
<td>• For patients with radiolucent stones in well-opacifying gallbladders, in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age</td>
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<tr>
<th>Dosing</th>
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| • Initially: 250mg twice daily for 2 weeks  
• Then, increase by 250 mg/day each week until recommended or maximum tolerated dose is reached  
• Refer to package insert for recommended dosing specifications |

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<th>Initial Authorization Criteria</th>
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| 1. Is the request for continuation of Chenodal (chenodiol) therapy?  
a. If yes, continue to Reauthorization  
b. If no, continue to #2  
2. Is the request for use to treat an FDA-approved indication? (Provide documentation of diagnosis)  
a. If yes, continue to #3  
b. If no, clinical review required  
3. Is there documentation that the member is not a candidate for surgery? (Provide rationale stating why member is not a candidate for surgery)  
a. If yes, continue to #4  
b. If no, clinical review required  
4. Does the member have documentation of a previous inadequate response, contraindication or intolerance to ursodiol? (Provide history of ursodiol use or contraindication to therapy)  
a. If yes, approve for 6 months unless otherwise specified  
b. If no, clinical review required |

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<th>Reauthorization Criteria</th>
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| 1. Does the member continue to meet the above criteria?  
a. If yes, continue to #2  
b. If no, clinical review required  
2. Has the member exceeded 24 months of therapy in this treatment course?  
a. If yes, clinical review required  
b. If no, approve for up to 12 months unless otherwise specified. Not to exceed 24 months of treatment |
Note:
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References:
Cholbam® (cholic acid)
Prior Authorization Guidelines

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

**FDA Approved Indication(s)**
- Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs)
- Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption

**Dosing**
- 10-15 mg/kg/day orally, in one or two divided doses
- Refer to package insert for specific dosing recommendations

**Initial Authorization Criteria**

1. Is the request for continuation of Cholbam (cholic acid) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have a diagnosis of peroxisomal disorder? (Provide documentation to support confirmation of diagnosis)
   a. If yes, continue to #4
   b. If no, continue to #7

4. Does the member have manifestations of at least one of the following? (Provide supporting documentation)
   - Liver disease (ex. jaundice or elevated liver enzymes)
   - Steatorrhea
   - Complications from decreased fat-soluble vitamin absorption
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the treatment intended for extrahepatic signs and/or symptoms of peroxisomal disorders? (Examples include psychomotor retardation, neurologic dysfunctions, hearing loss, visual abnormalities, and/or osteoporosis)
   a. If yes, clinical review required
   b. If no, continue to #6

Last Reviewed: 10/17/18
Effective Date: 1/1/19
6. Is the baseline liver function test and INR received? (Provide lab results)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the treatment being prescribed by, or in consult with, a medical geneticist, a pediatric gastroenterologist, a hepatologist, or a specialist experienced in treating inborn errors of metabolism?
   a. If yes, approve for 4 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member demonstrated a positive clinical response to therapy defined as decreased signs and/or symptoms from baseline? (Provide supporting documentation and updated liver function tests)
   a. If yes, continue to #3
   b. If no, clinical response required

3. Is the treatment being prescribed by, or in consult with, a medical geneticist, a pediatric gastroenterologist, a hepatologist, or a specialist experienced in treating inborn errors of metabolism?
   a. If yes, approve for 1 year unless otherwise specified
   b. If no, clinical review required

**Note:**
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**References:**
Compounded Medications
Prior Authorization Guidelines

Affected Medication(s)
• All compounded medications that are not commercially available

FDA Approved Indication(s)
• Refer to indications associated with active ingredient(s)

Dosing
• Refer to dosing associated with active ingredient(s)

Initial & Reauthorization Authorization Criteria

1. Are all active ingredients in the compounded medication FDA-approved?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Are all active ingredients being used for an FDA approved or major compendia supported indication? (Provide documentation of diagnosis and treatment plan)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is there an FDA-approved commercially available medication on the market for treatment of the requested condition?
   a. If yes, continue to #4
   b. If no, approve for 3 months unless otherwise specified

4. Is there documentation to support medical necessity over commercially available products? (Provide documentation supporting use over commercially available product)
   a. If yes, approve for 3 months unless otherwise specified
   b. If no, clinical review required
   c. Not applicable, approve for 3 months unless otherwise specified

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Corlanor® (ivabradine)
Prior Authorization Guidelines

Affected Medication(s)

- Corlanor oral tablet

FDA Approved Indication(s)

- To reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use

Dosing

- Initial: 5 mg twice daily with meals
- After 2 weeks, adjust dose to achieve a resting heart rate between 50-60 beats per minute (reference dosage adjustments in package insert)

Initial Authorization Criteria

1. Is the request for continuation of Corlanor (ivabradine) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have a left ventricular ejection fraction of 35% or less? (Provide lab for review)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member currently in sinus rhythm with a resting heart rate ≥ 70 beats per minute? (Provide heart rate for review)
   a. If yes, continue to # 5
   b. If no, clinical review required

5. Is the member on a maximally tolerated dose of a beta-blocker (i.e. metoprolol succinate, carvedilol, or bisoprolol) or have contraindication to their use? (Provide history of beta-blocker use or contraindication to therapy)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the treatment being prescribed by or in consult with a cardiologist?
   a. If yes, approve for 12 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 documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, clinical review required

2. Is the treatment being prescribed by or in consultation with a cardiologist?
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. Is documentation provided that the member is experiencing successful response to Corlanor? (Provide updated clinical information for review such as heart rate stabilization, improvement in HF symptoms, etc.)
   - a. If yes, approve for 12 months unless otherwise specified
   - b. If no, clinical review required

**Note:**

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**References:**

**Affected Medication(s)**

- Cresemba oral capsule

**FDA Approved Indication(s)**

- For patients 18 years of age and older for the treatment of invasive aspergillosis
- For patients 18 years of age and older for the treatment of invasive mucormycosis

**Dosing**

- Loading dose: Two 186 mg-capsules (372 mg) orally every 8 hours for 48 hours
- Maintenance dose: Two 186 mg-capsules (372 mg) orally once daily

**Authorization Criteria**

1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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, continue to #3
   b. If no, clinical review required

3. What is the requested diagnosis?
   a. Invasive aspergillosis, continue to #4
   b. Invasive mucormycosis, continue to #6

4. Is documentation of rationale for avoidance or contraindication to voriconazole received? (Provide supporting documentation)
   a. If yes, continue to #9
   b. If no, continue to #5

5. Did the member initiate Cresemba (isavuconazonium) therapy during the inpatient stay?
   a. If yes, continue to #9
   b. If no, clinical review required

6. Did the member have a trial with response to amphotericin B?
   a. If yes, continue to #9
   b. If no, continue to #7

7. Does the member have an intolerance or contraindication to amphotericin B? (Provide supporting documentation)
   a. If yes, continue to #9
   b. If no, continue to #8

8. Did the member initiate Cresemba (isavuconazonium) therapy during the inpatient stay?
   a. If yes, continue to #9
9. Is the treatment being initiated by an infectious disease specialist?
   a. If yes, approve for 3 months unless otherwise specified
   b. If no, clinical review required

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

Cystagon®, Procysbi® (cysteamine)
Prior Authorization Guidelines

Affected Medication(s)

- Cystagon oral capsule
- Procysbi oral capsule delayed release

FDA Approved Indication(s)

- **Cystagon**: Management of nephropathic cystinosis in children and adults
- **Procysbi**: Treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older

Dosing

- **Cystagon**:
  - Initially: Start at 1/4 to 1/6 of the maintenance dose and increase over 4-6 weeks
  - Maintenance dose: 1.30 grams/m²/day divided into four doses/daily
  - Use chart in package insert for weight based dosing
- **Procysbi**:
  - Initially: Start at 1/4 to 1/6 of the maintenance dose and increase over 4-6 weeks
  - Maintenance dose: 1.30 grams/m²/day divided into two doses/daily
  - Use chart in package insert for weight based dosing

Initial Authorization Criteria

1. Is the request for continuation of Cystagon (cysteamine) or Procysbi (cysteamine) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have confirmation of nephropathic cystinosis defined by elevated leukocyte cysteine levels (LCL) or presence of the CTNS gene mutation? (Provide documentation of elevated LCL or CTNS gene mutation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the request for Procysbi (cysteamine)?
   a. If yes, continue to #5
   b. If no, continue to #7

5. Is clinical rationale for avoiding Cystagon (cysteamine) provided? (Provide supporting documentation with inadequate response or intolerance)
   a. If yes, continue to #6
   b. If no, clinical review required
6. Is the member at least one year of age or older?
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the treatment being initiated by a specialist experienced in the management of nephropathic cystinosis? (Examples include endocrinologist, nephrologist, or urologist)
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have documentation of a positive clinical response to therapy as evidenced by a reduction in WBC cysteine levels compared to pre-treatment? (Provide supporting documentation for review)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the treatment being initiated by a specialist experienced in the management of nephropathic cystinosis? (Examples include endocrinologist, nephrologist, or urologist)
   a. If yes, approve for 12 months
   b. If no, clinical review required

Note:
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References:
# Cystaran® (cysteamine hydrochloride)
## Prior Authorization Guidelines

### Affected Medication(s)
- Cystaran ophthalmic solution

### FDA Approved Indication(s)
- Treatment of corneal cystine crystal accumulation in patients with cystinosis

### Dosing
- One drop in each eye, every waking hour

### Initial Authorization Criteria

1. Is the request for continuation of Cystaran (cysteamine hydrochloride) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have a presence of corneal cysteine accumulation? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the treatment being prescribed by, or in consultation with an ophthalmologist?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a presence of corneal cysteine accumulation? (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? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the treatment being prescribed by, or in consultation with an ophthalmologist?
   a. If yes, approve for 12 months unless otherwise specified

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Last Reviewed: 10/17/18
Effective Date: 1/1/19
b. If no, clinical review required

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**References:**


**Affected Medication(s)**
- Daliresp oral tablet

**FDA Approved Indication(s)**
- Treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

**Dosing**
- 500 mcg tablet daily
- Patients may initially start at 250 mcg daily for 4 weeks

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**Initial Authorization Criteria**

1. Is the request for continuation of Daliresp (roflumilast) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

2. Is Daliresp (roflumilast) being requested for COPD with associated bronchitis in a member with a history of exacerbations? (Provide documentation of diagnosis)
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. Does the member have a FEV1 of ≤ 50% predicted? (Provide documentation of baseline FEV1)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. Does the member have documentation of minimum 3 months trial or, intolerance, or contraindication to maintenance triple therapy with a long acting beta agonist, a long acting anti-muscarinic agonist, and an inhaled corticosteroid? (Provide supporting documentation of all therapies tried)
   - a. If yes, continue to #5
   - b. If no, clinical review required

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

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**Reauthorization Criteria**

1. Is Daliresp (roflumilast) being requested for COPD with associated bronchitis in a member with a history of exacerbations? (Provide documentation of diagnosis)
   - 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 decrease in COPD exacerbations from baseline? (Provide documentation of decreased COPD exacerbations)
   a. If yes, continue to #3
   b. If no, clinical review required

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

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**References:**

**Affected Medication(s)**

- Doptelet oral tablet
- Mulpleta oral tablet

**FDA Approved Indication(s)**

- For the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure

**Dosing**

- **Doptelet:**
  - Platelet count <40: 60 mg for 5 days
  - Platelet count 40-50: 40 mg for 5 days

- **Mulpleta**
  - 3 mg for 7 days 8 to 14 days prior to a scheduled procedure

**Authorization Criteria**

1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   - 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, continue to #3
   - b. If no, clinical review required

3. Does the member have a platelet count of <50 x 10⁹? (Provide documentation of platelet count)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. Does the member have a planned medical or dental procedure with intermediate-to-high bleeding risk within the next 30 days? (Provide date and type of scheduled procedure for review)
   - a. If yes, continue to #5
   - b. If no, clinical review required

5. Is the treatment being prescribed by, or in consultation with, a hematologist, hepatologist, or gastroenterologist?
   - a. If yes, continue to #6
   - b. If no, clinical review required

6. What is the requested medication?
   - a. Doptelet (avatrombopag maleate), continue to #7
   - b. Mulpleta (lusutrombopag), continue to #8
7. Is the treatment plan to begin therapy 10-13 days prior to the scheduled procedure and undergo the procedure within 5 to 8 days after the last dose? (Provide documentation of treatment plan and date of scheduled procedure)
   a. If yes, approve for 5 days
   b. If no, clinical review required

8. 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? (Provide documentation of treatment plan and date of scheduled procedure)
   a. If yes, approve for 7 days
   b. If no, clinical review required

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References:
## Affected Medication(s)
- Dupixent subcutaneous solution

## FDA Approved Indication(s)
- Treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable

## Dosing
- Initial: 600 mg (two 300 mg injections) subcutaneously
- Maintenance: 300mg subcutaneously every other week

## Initial Authorization Criteria

1. Is the request for continuation of Dupixent (dupilumab) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have at least 10% body surface area involvement? (Provide documentation of body surface area affected)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have a documented trial with insufficient response, or intolerance, or contraindication to both a high-potency topical steroid (i.e. clobetasol 0.05%, fluocinonide 0.1%, halobetasol 0.05%, or betamethasone dipropionate 0.05%) and a topical calcineurin inhibitor (i.e. tacrolimus or pimecrolimus)? (Provide supporting documentation of all therapies tried)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have a documented trial with insufficient response or intolerance to at least one systemic immunomodulatory agent (i.e. azathioprine, cyclosporine, methotrexate, or mycophenolate)? (Provide supporting documentation of all therapies tried)
   a. If yes, continue to #7
   b. If no, continue to #6

6. Does the member have a documented clinical rationale for avoidance or contraindication to systemic immunomodulatory agents? (Provide documentation to support avoidance and/or contraindication)
   a. If yes, continue to #7
b. If no, clinical review required

7. Does the member have a documented trial with insufficient response, intolerance, or contraindication to phototherapy? (Provide documentation to support insufficient response, intolerance, and/or contraindication)
   
   a. If yes, continue to #8
   
   b. If no, clinical review required

8. Is Dupixent (dupilumab) being prescribed by or in consultation with a dermatologist, allergist, or immunologist?
   
   a. If yes, approve for 6 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 documentation of diagnosis)
   
   a. If yes, continue to #2
   
   b. If no, clinical review required

2. Is clinical documentation confirming a reduction in number flares and reduction of the percentage of body surface area affected provided? (Provide documentation to support clinical response to therapy)
   
   a. If yes, continue to #3
   
   b. If no, clinical review required

3. Is Dupixent (dupilumab) being prescribed by or in consultation with a dermatologist, allergist, or immunologist?
   
   a. If yes, approve for 12 months unless otherwise specified
   
   b. If no, clinical review required

**Note:**

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**References:**


Affected Medication(s)
- Epidiolex (cannabidiol)

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 request for continuation of Epidiolex (cannabidiol) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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 the member currently taking at least one other antiepileptic drug with inadequate response? (Provide documentation of antiepileptic therapy and seizure frequency)
   a. If yes, continue to #5
   b. If no, clinical review required

5. For members with LGS, has the member had a previous trial with inadequate response, intolerance, or contraindication to clobazam? (Provide documentation of trial with inadequate response)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Will the member continue therapy with at least one other antiepileptic drug in combination with Epidiolex (cannabidiol)?
   a. If yes, continue to #7
   b. If no, clinical review required

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

1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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? (Significant clinical response is defined by a decrease in seizure frequency compared to pre-treatment baseline)
   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

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References:

Epogen®, Procrit®, Retacrit® (epoetin alfa)  
Prior Authorization Guidelines

**Affected Medication(s)**
- Epogen (epoetin alfa) injection solution
- Procrit (epoetin alfa) injection solution
- Retacrit (epoetin alfa-epbx) injection solution

**FDA Approved Indication(s)**
- Treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis 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. 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 request for continuation of epoetin alfa therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

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

4. Does the member have a serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%?
   (Provide labs for review)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have a hemoglobin (hb) < 10 g/dL and/or Hematocrit (Hct) < 30%?
   a. If yes, continue to #7
   b. If no, continue to #6
6. Is the medication being requested to reduce allogeneic blood transfusions in elective, non-cardiac, non-vascular surgery?
   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?
   a. If yes, continue to #8
   b. If no, clinical review required

8. Is epoetin alfa-apbx being requested?
   a. If yes, continue to #10
   b. If no, continue to #9

9. Does the member have a contraindication or history of intolerance to a trial of epoetin alfa-apbx? (Provide supporting documentation of contraindication and/or intolerance)
   a. If yes, continue to #10
   b. If no, clinical review required

10. Which indication is epoetin alfa being requested for? (Record submitted diagnosis and review all criteria based on the submitted diagnosis)
    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 include: exertional dyspnea, dyspnea at rest, fatigue, lethargy, confusion, etc.) (Provide supporting documentation of symptoms)
   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 serum erythropoietin level for review)
   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 members endogenous serum erythropoietin level < 500 mUnits/mL? (Provide serum erythropoietin level for review)
### Anemia secondary to chemotherapy treatment

1. Is the member receiving concurrent myelosuppressive chemotherapy for non-myeloid malignancies?
   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 documentation of treatment plan)
   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 serum erythropoietin level or current zidovudine dose for review)
   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 with Hb and Hct lab values for review)
   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 documentation of diagnosis)
   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 contradiction to ALL standard treatment options for the requested indication (Provide all prior treatment history, contraindication if appropriate, and treatment plan)
   a. If yes, approve for 45 days unless otherwise specified
   b. If no, clinical review required

### Reauthorization Criteria

1. Was the last dose of Epogen/Procrit (epoetin alfa) less than 60 days ago? (Provide date of last dose)
   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? (Provide documentation of clinical response)
   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 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], "gasiing syndrome" [central nervous system depression, metabolic acidosis, gasping respirations] due to benzyl alcohol preservative, etc)
   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)? (Provide updated lab result for review)
   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 lab result for review)
   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?
   a. If yes, continue to #7
   b. If no, clinical review required

7. 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
- Use supported my major compendia
  a. If yes, approve for 45 days unless otherwise specified
  b. If no, clinical review required

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**References:**

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) epoetin 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.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Myeloproliferative Neoplasms Version 2.2018. 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


# Exjade®, Jadenu® (deferrioxime)

## Prior Authorization Guidelines

**Last Reviewed:** 10/17/18  
**Effective Date:** 1/1/19

### Affected Medication(s)

- Exjade oral tablet for suspension
- Jadenu oral tablet/sprinkles granules

### FDA Approved Indication(s)

- Treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older
- Treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L

### Dosing

- Refer to package insert for dosing recommendations

### Initial Authorization Criteria

1. **Is the request for continuation of Exjade or Jadenu (deferrioxime) therapy?**
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. **Is the treatment being prescribed by, or in consult with a hematologist?**
   a. If yes, continue to #4
   b. If no, clinical review required

4. **Is the member concurrently using other iron chelators (Examples include: Ferriprox, Desferal, Depen, and Cuprimine)?**
   a. If yes, clinical review required
   b. If no, continue to #5

5. **What is the indication that the medication is being requested for?**
   a. Chronic iron overload due to blood transfusions, see corresponding criteria
   b. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT), see corresponding criteria

#### Chronic iron overload due to blood transfusions

1. **Is the member 2 years of age or older?**
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member have a history of transfusion with at least 100mL/kg of packed red blood cells? (Provide supporting documentation for review)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is serum ferritin consistently greater than 1000mcg/L? (Provide supporting labs for review)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

1. Is the member 10 years of age or older?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a serum ferritin level of > 300 mcg/L and a liver iron concentration of ≥ 5 mg Fe/g of liver dry weight? (Provide documentation of lab result)
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the treatment being prescribed by, or in consult with a hematologist?
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the member concurrently using other iron chelators?
   a. If yes, clinical review required
   b. If no, continue to #4

4. What is the indication that the medication is being requested for?
   a. Chronic iron overload due to blood transfusions, see corresponding criteria
   b. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT), see corresponding criteria

Chronic iron overload due to blood transfusions

1. Does the member have a serum ferritin level ≥ 500 mcg/L? (Provide documentation of serum ferritin level within the past 30 days)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required
Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

1. Does the member have a liver iron concentration of $\geq$ 3 mg Fe/g of liver dry weight? (Provide documentation of lab result within the past 90 days)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

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References:
Ferriprox® (deferiprone)
Prior Authorization Guidelines

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

<table>
<thead>
<tr>
<th>FDA Approved Indication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Dosing</th>
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<tbody>
<tr>
<td>• 25 mg/kg to 33 mg/kg orally three times daily</td>
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<tr>
<th>Initial Authorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the request for continuation of Ferriprox (deferiprone) therapy?</td>
</tr>
<tr>
<td>a. If yes, continue to Reauthorization</td>
</tr>
<tr>
<td>b. If no, continue to #2</td>
</tr>
<tr>
<td>2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)</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. Does the member have an ANC greater than 1.5 x 10^9/L? (Provide ANC level for review)</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. Does the member have a trial with inadequate response, intolerance, or contraindication to an iron chelator? (Examples include Desferal, Exjade, or Jadenu) (Inadequate response defined as serum ferritin &gt; 2,500 mcg/L) (Provide documentation of trial and response, intolerance, or contraindication)</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. Is the treatment being prescribed by, or in consultation with, a hematologist?</td>
</tr>
<tr>
<td>a. If yes, approve for 12 months unless otherwise specified</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Reauthorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the request for use to treat an FDA approved indication? (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>
</tbody>
</table>
2. Has the member had a positive clinical response to therapy as defined by a $\geq 20\%$ decline in serum ferritin within one year of starting therapy? (Provide supporting documentation for review)
   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 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:

1. Ferriprox [prescribing information]. Toronto, Ontario: ApoPharma USA, Inc.; May 2017
Fertility Agents
Prior Authorization Guidelines

**Affected Medication(s)**

- Bravelle (urofollitropin) subcutaneous powder for solution
- Cetrotide (cetrorelix acetate) subcutaneous powder for solution
- chorionic gonadotropin intramuscular powder for solution
- clomiphene oral tablet
- Crinone 8% (progesterone) vaginal gel
- Endometrin (progesterone) vaginal tablet
- Follistim AQ (follitropin beta) subcutaneous solution
- ganirelix acetate subcutaneous solution
- Gonal-F (follitropin alfa) subcutaneous powder for solution
- Menopur (menotropins) subcutaneous powder for solution
- Novarel (chorionic gonadotropin) intramuscular powder for solution
- Ovidrel (chorionic gonadotropin alfa, recombinant) subcutaneous solution
- Pregnyl (chorionic gonadotropin) intramuscular powder for solution
- Serophene (clomiphene) oral tablet

**FDA Approved Indication(s)**

- Refer to package insert for specific indications for each medication

**Dosing**

- Refer to corresponding package insert for specific dosing recommendations

**Authorization Criteria**

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

2. **Does the member meet one or more of the following conditions?**

   **Female**
   - 35 years of age or younger with failure to conceive after regular unprotected sexual intercourse for 1 year or more
   - 35 years of age or older with failure to conceive after regular unprotected sexual intercourse for 6 months or more
   - Prior cycle of in vitro fertilization or intracytoplasmic sperm injection with failure
   - Prior cycle of artificial insemination with the absence of an opposite-sex partner with failure
   - Anticancer therapy induced ovulatory failure (e.g., alkylating agents)
   - Impending infertility due to planned cancer treatment with curative intent (e.g., chemotherapy or oophorectomy)
   - Female with history of bilateral oophorectomy

   **Male Partner**
   - Infertility due to anticancer treatment (e.g., orchiectomy or chemotherapy)
   - With non-obstructive azoospermia or severe oligospermia

Last Reviewed: 12/19/18
Effective Date: 1/1/19
• Paraplegia and require sperm retrieval to achieve pregnancy
  a. If yes, approve for 12 months or up to duration of benefit
  b. If no, continue to #3

3. Is the male partner HIV positive and meet BOTH the following?
  • Adherent with antiretroviral therapy regimen
  • Washed sperm needed for insemination to prevent HIV transmission to female partner
  a. If yes, approve for 12 months or up to duration of benefit
  b. If no, clinical review required

*Please refer to medical handbook for more information

Note:
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type 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:
   2016.
6. Endometrin (progesterone) [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals Inc. October
   2018.
7. Follistim AQ (follitropin beta) [Prescribing Information]. Whitehouse Station, NJ: Organon USA Inc. December
   2014.
    November 2018.
    June 2018.
13. Pregnyl (chorionic gonadotropin) [Prescribing Information]. Whitehouse Station, NJ: Organon USA Inc.
    January 2015.
Galafold® (migalastat hydrochloride)
Prior Authorization Guidelines

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Galafold oral capsule</td>
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<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>
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<table>
<thead>
<tr>
<th>Dosing</th>
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<tbody>
<tr>
<td>• 123 mg orally once every other day</td>
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<table>
<thead>
<tr>
<th>Initial Authorization Criteria</th>
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</thead>
<tbody>
<tr>
<td>1. Is the request for continuation of Galafold (migalastat hydrochloride) therapy?</td>
</tr>
<tr>
<td>a. If yes, continue to Reauthorization</td>
</tr>
<tr>
<td>b. If no, continue to #2</td>
</tr>
<tr>
<td>2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)</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 member 18 years of age or older?</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. Does the member have a diagnosis of Fabry disease that is confirmed by biochemical and/or molecular genetic testing? (Provide supporting documentation including baseline kidney interstitial capillary cell globotriaosylceramide (KIC GL-3))</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 GLA variant based on in vitro assay that is considered amenable? (Provide documentation of amenable GLA variant)</td>
</tr>
<tr>
<td>a. If yes, continue to #6</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td>6. Is the member female?</td>
</tr>
<tr>
<td>a. If yes, continue to #7</td>
</tr>
<tr>
<td>b. If no, continue to #8</td>
</tr>
<tr>
<td>7. Does the member have documented clinical manifestations of Fabry disease? (Provide documentation of disease manifestations e.g. cardiac, renal, neurologic)</td>
</tr>
<tr>
<td>a. If yes, continue to #8</td>
</tr>
<tr>
<td>b. If no, clinical review required</td>
</tr>
</tbody>
</table>
8. Will Galafold (migalastat hydrochloride) be used in combination with other enzyme replacement therapy for treatment of Fabry disease?
   a. If yes, clinical review required
   b. If no, continue to #9

9. 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, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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 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, clinical review required

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, clinical review required

Note:
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References:

1. Galafold [Product Information], Amicus Therapeutics U.S., Inc. Cranbury, NJ. August 2018
**Gattex® (teduglutide)**

**Prior Authorization Guidelines**

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### Affected Medication(s)

- Gattex kit for subcutaneous administration

### FDA Approved Indication(s)

- Treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support

### Dosing

- 0.05 mg/kg body weight administered by subcutaneous injection once daily

### Initial Authorization Criteria

1. Is the request for continuation of Gattex (teduglutide) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

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

4. Has the member been dependent on parenteral nutrition support at least 3 times a week for at least 12 consecutive months prior to planned date of Gattex (teduglutide) initiation? (Provide documentation of parenteral nutritional support history and frequency)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the treatment being prescribed by, or in consultation with, a gastroenterologist?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member’s requirement for parenteral nutritional support decreased at least 1 day per week from pre-treatment baseline? (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 gastroenterologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:
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References:
Glucosylceramide Synthase Inhibitors
Prior Authorization Guidelines

Affected Medication(s)

- Cerdelga (eliglustat) oral capsule
- Zavesca (miglustat) oral capsule

FDA Approved Indication(s)

- **Cerdelga**: Long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test
- **Zavesca**: Monotherapy for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy (examples include: imiglucerase, velaglucerase alfa, or taliglucerase alpha) is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access)

Dosing

- **Cerdelga (eliglustat)**:
  - Extensive metabolizers and intermediate metabolizers: 84 mg twice daily
  - Poor metabolizers: 84 mg once daily
  - May be necessary to reduce dose in patients on concomitant CYP2D6 or CYP3A4 inhibitors
- **Zavesca (miglustat)**: 100 mg three times daily
  - May be necessary to reduce dose in patients with adverse reactions or renal insufficiency

Initial Authorization Criteria

1. Is the request for continuation of glucosylceramide synthase inhibitor therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have a diagnosis of type 1 Gaucher disease? (Provide genetic testing result for review)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Has the member had a previous inadequate response, intolerance, or contraindication (i.e. due to allergy, hypersensitivity, or poor venous access) to enzyme replacement therapy (i.e. velaglucerase alfa, imiglucerase, or taliglucerase alpha)? (Provide history of enzyme replacement therapy or contraindication to use)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
   a. If yes, continue to #6

Last Reviewed: 10/3/18
Effective Date: 1/1/19
b. If no, clinical review required

6. Is the request for Cerdelga (eliglustat)?
   a. If yes, continue to #7
   b. If no, approve for 3 months unless otherwise specified

7. For approval of Cerdelga (eliglustat): Is the member a CYP2D6 poor metabolizer, extensive metabolizer, or intermediate metabolizer as confirmed using an FDA-cleared test?
   a. If yes, approve for 3 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the treatment being prescribed by or in consultation with a provider who specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is there documentation that the member has a clinical response to therapy defined by an improvement in symptoms and quality of life?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:
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References:

## Affected Medication(s)
- Rilutek oral tablet
- Tiglutik oral suspension

## FDA Approved Indication(s)
- Treatment of amyotrophic lateral sclerosis (ALS)

## Dosing
- 50 mg taken orally twice daily

## Initial Authorization Criteria
1. Is the request for continuation of Rilutek (riluzole) or Tiglutik (riluzole) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Has the patient had a diagnosis of ALS for less than 5 years? (Provide supporting documentation for review)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is medical rationale provided on why the member is unable to use generic riluzole? (Provide supporting documentation with medical rationale)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Is the treatment being prescribed by, or in consultation with a neurologist?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Has the member demonstrated a positive response to therapy as defined by stabilization in symptoms? (Providing supporting documentation for review)
3. Is the treatment being prescribed by, or in consultation with a neurologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

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References:
Affected Medication(s)

- Eligard (leuprolide acetate) subcutaneous powder for suspension
- Leuprolide acetate solution for subcutaneous injection
- Lupron (leuprolide acetate) subcutaneous powder for suspension
- Lupron Depot (leuprolide acetate) for intramuscular injection
- Lupron Depot-Ped (leuprolide acetate) for intramuscular injection
- Lupaneta Pack (leuprolide acetate and norethindrone acetate)
- Synarel (nafarelin acetate) nasal spray
- Trelstar (triptorelin pamoate) intramuscular powder for suspension
- Triptodur (triptorelin) intramuscular powder for suspension

FDA Approved Indication(s)

- **Eligard**: For the palliative treatment of advanced prostate cancer
- **Leuprolide acetate**: For the palliative treatment of advanced prostate cancer
- **Lupron**: For the palliative treatment of advanced prostatic cancer
- **Lupron Depot**: (endometriosis, duration is 6 months, preop, duration is 1 dose)
  - For management of endometriosis, including pain relief and reduction of endometriotic lesions
  - For initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms when use in combination with norethindrone acetate
  - For the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata when used concomitantly with iron therapy
- **Lupron Depot-Ped**: For the treatment of children with central precocious puberty (CPP)
- **Lupaneta Pack**: For initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms
- **Synarel**: For the treatment of central precocious puberty (gonadotropin-dependent precocious puberty) in children of both sexes
- **Trelstar**: For the palliative treatment of advanced prostate cancer
- **Triptodur**: For the treatment of pediatric patients 2 years of age and older with central precocious puberty

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of the same GnRH agonist therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. What diagnosis is the medication being requested for?
   a. Anemia associated with uterine leiomyomata (fibroids), continue to corresponding criteria
   b. Endometriosis, continue to corresponding criteria
   c. Central precocious puberty, continue to corresponding criteria
   d. Gender dysphoria, continue to corresponding criteria
   e. Oncology indication, continue to corresponding criteria

**Anemia Associated with Uterine Leiomyomata (fibroids)**

1. Is the member currently taking adequate iron supplementation with insufficient response? (Provide documentation trial with inadequate response)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Will the member continue to take iron supplementation throughout therapy? (Provide documentation of complete treatment regimen)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the member scheduled to have surgical removal of fibroids within the next 6 months? (Provide documentation of surgical date for review)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the medication being prescribed by, or in consultation with, a gynecologist?
   a. If yes, approve for up to 6 months unless otherwise specified
   b. If no, clinical review required

**Endometriosis**

1. Does the member have a previous trial with inadequate response, intolerance or contraindication to continuous oral contraception? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Will the member use Lupenata Pack or use the requested medication in combination with add-back progesterone therapy to avoid hypoestrogenic effects? (Provide documentation of complete treatment regimen)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the medication being prescribed by, or in consultation with, a gynecologist?
   a. If yes, approve for 6 months unless otherwise specified
   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 documentation of serum LH levels)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the request for Triptodur, or Synarel?
   a. If yes, continue to #4
   b. If no, continue to #5

4. Does the member have a previous trial with inadequate response, intolerance, or contraindication to treatment with Lupron?
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the medication prescribed by, or in consultation with, a pediatric endocrinologist?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

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**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?
   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 being prescribed by, or in consultation with, an endocrinologist?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

**Oncology Indication**

1. Is the medication being requested for an indication supported by the National Comprehensive Cancer Network (NCCN) 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 #2
   b. If no, clinical review required

2. Does the member have Karnofsky Performance Status greater or equal to 50% OR Eastern Cooperative Oncology Group (ECOG) performance status of 0-2? (Provide performance status 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 an oncologist?
   a. If yes, approve for 4 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the request for reauthorization of Synarel?
   a. If yes, clinical review required
   b. If no, continue to #3

3. What diagnosis is the medication being requested for?
   a. Anemia associated with uterine leiomyomata (fibroids), clinical review required
   b. Endometriosis, continue to corresponding criteria
   c. Central precocious puberty, continue to corresponding criteria
   d. Gender dysphoria, continue to corresponding criteria
   e. Oncology indication, continue to corresponding criteria

**Endometriosis**

1. Does the member show a positive clinical response to therapy as defined by a decrease in endometriotic pain and/or a reduction of endometriotic lesions? (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 gynecologist?
   a. If yes, approve for 6 months unless otherwise specified
   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 response required

Oncology indication
1. Does the member show a positive clinical response to therapy defined by documentation of disease responsiveness? (Examples include reduction in PSA to normal values, serum testosterone level ≤50 ng/dL, etc.) (Provide supporting documentation of disease response)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the medication being prescribed by, or in consultation with, an oncologist?
   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:
1. Eligard [Product Information], Tolmar Pharmaceuticals, Inc. Fort Collins, CO. March 2018
2. Lupron [Product Information], TAP Pharmaceutical Products Inc. Lake Forest, IL. February 2008
3. Lupron Depot [Product Information], AbbVie Inc. North Chicago, IL. November 2018
4. Lupron Depot- Ped [Product Information], AbbVie Inc. North Chicago, IL. November 2018
5. Lupaneta [Product Information], AbbVie Inc. North Chicago, IL. November 2018
7. Trelstar [Product Information], Allergan, Inc. Bloomington, IN. January 2018
8. Triptodur [Product Information], Arbor Pharmaceuticals, LLC. Atlanta, GA. August 2018
Growth Hormone
Prior Authorization Guidelines

Affected Medication(s)

- Genotropin
- Humatrope
- Norditropin
- Nutropin
- Omnitrope
- Saizen
- Serostim
- Zomacton
- Zorbtive

Indication(s)

- For the treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi syndrome (PWS), Small for Gestational Age (SGA), Turner syndrome (TS), and Idiopathic Short Stature (ISS)
  - Genotropin, Omnitrope
- For the treatment of children with short stature or growth failure associated with GHD, TS, ISS, short stature homeobox-containing gene (SHOX) deficiency, and failure to catch up in height after SGA
  - Humatrope
- For the treatment of pediatric members with growth failure due to inadequate secretion of endogenous growth hormone (GH), short stature associated with Noonan syndrome (NS), short stature associated with TS, SGA with no catch-up growth by age 2 to 4 years, ISS, and growth failure due to PWS
  - Norditropin
- For the treatment of children with growth failure due to GHD, ISS, TS, and chronic kidney disease (CKD) up to the time of renal transplantation
  - Nutropin AQ
- For the treatment of pediatric members with growth failure due to inadequate secretion of endogenous GH, short stature associated with TS, ISS, short stature or growth failure in SHOX deficiency, and short stature born SGA with no catch-up growth by 2 years to 4 years
  - Zomacton
- For the treatment of children with growth failure due to GHD
  - Saizen
- For the treatment of adults with either adult onset or childhood onset GHD
  - Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen
- For replacement of endogenous GH is adults with GH deficiency
  - Norditropin, Zomacton
- For the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Concomitant antiretroviral therapy is necessary
  - Serostim
- For the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support
  - Zorbtive

Dosing

- Refer to corresponding package insert for dosing recommendations

Initial Authorization Criteria

1. 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

Last Reviewed: 12/19/18
Effective Date: 1/1/19
2. Is the treatment being prescribed by, or in consultation with, an appropriate specialist (e.g. endocrinologist, HIV specialist, gastroenterologist, etc.)?
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the requested medication either Norditropin or Omnitrope?
   a. If yes, continue to #5
   b. If no, continue to #4

4. Does the member have a trial with insufficient response, an intolerance, or contraindication to both Norditropin and Omnitrope OR use is inappropriate for FDA-indication? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the request for one of the below indications AND matches the medication’s FDA-labeled indications for use? (Provide documentation of diagnosis, patient weight, and requested dosing/dosing frequency)
   - Growth failure due to growth hormone deficiency (GHD) in pediatrics
   - Growth failure due to Prader-Willi Syndrome (PWS) in pediatrics
   - Short stature born small for gestational age (SGA) with no catch-up growth by age 2 to 4 years in pediatrics
   - Short stature associated with Turner's Syndrome (TS) in pediatrics
   - Idiopathic short stature (ISS)
   - Short stature homeobox-containing gene (SHOX) deficiency in pediatrics
   - Short stature associated with Noonan Syndrome (NS) in pediatrics
   - Chronic renal insufficiency in pediatrics
   - Adult acquired GHD
   - GHD in adults who had childhood onset GHD
   - Acquired immunodeficiency syndrome (AIDS) wasting or cachexia
   - Short bowel syndrome
   a. If yes, continue to corresponding criteria
   b. If no, clinical review required

Growth hormone deficiency (GHD) in pediatrics
1. Does the member have auxologic evidence of short stature or growth failure defined 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 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
   - In the absence of short stature, height velocity < −2 SD below mean over 1 year OR < −1.5 SD below mean over 2 years
   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 skeletal disorders)
   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)
   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)
   • Height < −1.5 SD below mid-parental height (average of mother’s/father’s heights)
   • Height < −2 SD below mean of same gender and chronological age
   • Height velocity < −2 SD below mean over 1 year OR < −1.5 SD below mean over 2 years
   a. If yes, clinical review required
   a. If no, continue to #4
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

### Small for gestational age (SGA) in pediatrics

1. Was the member born SGA as defined as weight and/or length <-2 SD below age mean? (Provide documentation of birth weight and length)
   a. If yes, continue to #2
   b. If no, clinical review required

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

3. Did the member fail to achieve postnatal catch-up growth with height remaining <-2 SD below age mean? (Provide supporting documentation)
   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. 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

### Idiopathic short stature (ISS) in pediatrics

1. Does the member have ISS as defined as height <-2.25 SDs of mean for age in the absence of any endocrinal, metabolic, or other cause that explains short stature? (Provide supporting documentation)
   a. If yes, continue to #2
2. Is the member’s predicted adult height below the normal range (less than 63 inches for males or less than 59 inches for females)? (Provide documentation of predicted adult height)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Has the provider thoroughly informed the member/member’s family of the risks versus benefits and limitations of growth hormone therapy? (Provide supporting documentation)
   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

### SHOX deficiency in pediatrics

1. Does the member have SHOX deficiency as diagnosed by DNA analysis? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

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

3. 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?
   a. If yes, continue to #4
   b. If no, clinical review required
4. Has the member been screened for thyroid abnormalities?
   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

**Chronic renal insufficiency in pediatrics**

1. Does the member have chronic renal insufficiency with an estimated GFR <75 mL/min per 1.73 m²? (Provide documentation of GFR)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is there evidence of growth impairment, defined as height Z-score <-1.88 (3rd percentile) or a height velocity <-2 SDs for age? [Note: Z-score calculated using CDC height chart] (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Have other causes of short stature been ruled out and/or corrected prior to consideration of GH therapy? (i.e. acidosis, secondary hyperparathyroidism, malnutrition, zinc deficiency)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have severe hyperparathyroidism (CKD stage 2-4: PTH >400 pg/mL or CKD stage 5: PTH >900 pg/mL)?
   a. If yes, clinical review required
   b. If no, continue to #5

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 member pre-kidney transplantation? (Provide supporting documentation)
   a. If yes, approve for 3 months unless otherwise specified
   b. If no, clinical review required

**Adult onset GHD**

1. Does the member have all of the following? (Provide supporting documentation)
   - Confirmed panhypopituitarism (deficiency in ≥3 pituitary hormones)
   - Serum IGF-1 levels < 2.5 percentile
   - Irreversible pituitary disease or physical trauma (e.g. pituitary tumor, pituitary surgical damage, irradiation, sarcoidosis)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, continue to #2
2. Does the member have documentation of at least TWO of the following? (Provide supporting documentation)
   - Deficient in at least > 1 other pituitary hormone and IGF-1 <50th percentile
   - Insulin tolerance test (ITT) with peak growth hormone (GH) ≤ 5.0 mcg/L
   - Glucagon stimulation test with serum GH < 3.0 mcg/L (or <1 mcg/L if obese) and arginine-L-DOPA stimulation test with serum GH < 1.5 mcg/L
   - Macimorelin stimulation test with serum GH <2.8 ng/mL
   a. If yes, continue to #3
   b. If no, clinical review required

3. Was member’s GHD is caused by traumatic brain injury or subarachnoid hemorrhage?
   a. If yes, continue to #4
   b. If no, approve for 6 months unless otherwise specified

4. Was GH stimulation test performed at least 12 months after the event? (Provide supporting documentation)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Adults with childhood onset GHD

1. Was the member treated with GH replacement for conditions other than for GHD (i.e. TS, ISS, PWS, etc)?
   a. If yes, clinical review required
   b. If no, continue to #2

2. Does the member have childhood onset GHD from a known genetic mutation, embryopathic/congenital defect, or irreversible hypothalamic-pituitary structural damage AND has panhypopituitarism (≥ 3 pituitary hormone deficiencies) with IGF-1 < 2.5 percentile? (Provide supporting documentation)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, continue to #3

3. Has the member completed retesting with GH stimulation test? [Note: Re-testing should be completed after final height achieved and GH stopped for at least 1 month] (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Upon re-testing, does the member have confirmation of GHD through at least TWO of the following? (Provide supporting documentation)
   - Deficient in at least one other pituitary hormone and IGF-1 <50th percentile
   - Insulin tolerance test (ITT) with peak growth hormone (GH) ≤ 5.0 mcg/L
   - Glucagon stimulation test with serum GH < 3.0 mcg/L (or <1 mcg/L if obese) and arginine-L-DOPA stimulation test with serum GH < 1.5 mcg/L
   - Macimorelin stimulation test with serum GH <2.8 ng/mL
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

HIV-associated wasting or cachexia
1. Does the member have HIV and one the following? (Provide supporting documentation)
   - 10% unintentionally weight loss over 12 months
   - 7.5% unintentional weight loss over 6 months
   - 5% body cell mass (BCM) loss within 6 months
   - Men: BCM <35% total body weight and body mass index (BMI) <27 kg/m²
   - Women: BCM <23% total body weight and BMI <27 kg/m²
   - BMI <20 kg/m²
   a. If yes, continue to #2
   b. If no, clinical review required

2. Have other possible illnesses aside from HIV/AIDS been ruled out as the cause of weight loss?
   a. If yes, continue to #3
   b. If no, clinical review required

3. Will the member receive antiretroviral therapy for HIV/AIDS concomitantly with the requested medication? (Provide supporting documentation of treatment plan)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have a documented trial with insufficient response, an intolerance, or contraindication to at least one appetite stimulants and/or anabolic agents? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the member less than 18 years of age?
   a. If yes, clinical review required
   b. If no, approve for 3 months unless otherwise specified

### Short bowel syndrome (SBS)

1. Does the member have nutritional malabsorption due to loss of function or portion of the intestines? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member currently receiving specialized nutrition support (i.e. high carbohydrate, low-fat diet, enteral feedings, parenteral nutrition)? (Provide supporting documentation of nutrition support)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Has the member tried and failed traditional therapies for the management of SBS (e.g. acid suppressing agents, antidiarrheals, or octreotide)? (Provide supporting documentation)
   a. If yes, approve for 1 month unless otherwise specified
   b. If no, clinical review required
Reauthorization Criteria

1. Is the request for one of the below indications AND matches the medication’s FDA-labeled indications for use? (Provide documentation of diagnosis, patient weight, and requested dosing/dosing frequency)
   a. GHD, PWS, SGA, ISS, TS, SHOX, NS in pediatrics, continue to the corresponding criteria
   b. CKD in pediatrics, continue to corresponding criteria
   c. Adults with GHD, continue to corresponding criteria
   d. Acquired immunodeficiency syndrome (AIDS) wasting or cachexia, continue to corresponding criteria
   e. Short bowel syndrome, clinical review required

GHD, PWS, SGA, ISS, TS, SHOX, NS in pediatrics

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

2. 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 #3
   b. If no, clinical review required

3. Is the member’s IGF-I level maintained between 0 to +2 SD for age? (Provide supporting documentation)
   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 12 months unless otherwise specified
   b. If no, clinical review required

CKD in pediatrics

1. Is the member pre-renal transplantation? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is there documentation of 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. Is the member still below target height based on midparental height or 50th percentile for age? (Provide supporting documentation)
   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, continue to #5
   b. If no, clinical review required

5. Does the member have severe hyperparathyroidism (CKD stage 2-4: PTH >400 pg/mL or CKD stage 5: PTH >900 pg/mL)?
   a. If yes, clinical review required
   b. If no, approve for 12 months unless otherwise specified

Adults with GHD (childhood or adult onset)

1. Is the member’s IGF-1 concentration within the age-specific range of normal? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is there documentation the member is benefitting from GH therapy (e.g. increase quality of life, improvements in body composition, cardiovascular risk markers, etc)? (Provide supporting documentation)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

HIV-associated wasting or cachexia

1. Is there documentation of positive response from therapy (i.e. increase in body weight or BCM)? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member continue to have evidence of wasting? (Provide supporting documentation)
   a. If yes, approve for 12 weeks unless otherwise specified (maximum total duration 48 weeks)
   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:
Hepatitis C Direct Acting Antivirals
Prior Authorization Guidelines

Affected Medication(s)

• Epclusa (sofosbuvir/velpatasvir) oral tablet
• Mavyret (glecaprevir/pibrentasvir) oral tablet
• Sofosbuvir/velpatasvir oral tablet
• Vosevi (sofosbuvir/velpatasvir/voxilaprevir) oral tablet

FDA Approved Indication(s)

• **Epclusa**: Treatment of chronic hepatitis C (HCV) genotype 1, 2, 3, 4, 5, or 6 infection in adults without cirrhosis or with compensated cirrhosis or in combination with ribavirin in patients with decompensated cirrhosis

• **Mavyret**: Treatment of chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection in adults without cirrhosis or with compensated cirrhosis (Child-Pugh A); HCV genotype 1 infection in adults previously treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both

• **Vosevi**: Treatment of adults with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor or who have genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor

Dosing

• Refer to indication specific compendia supported dosing

Initial Authorization Criteria

1. Is the request for use to treat chronic hepatitis C? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the request for continuation of a hepatitis C regimen?
   a. If yes, clinical review required
   b. If no, continue to #3

3. Have all of the following pre-treatment test results been submitted? (Provide documentation of all requested test results)
   • HCV genotype
   • Fibrosis staging
   • Quantifiable baseline HCV RNA (within the last 12 months)
   • HIV status
   • HBV serology
   • Treatment history and outcome
   a. If yes, continue to #4
   b. If no, clinical review required
4. If positive HBsAg or positive anti-HBc with negative HBsAb: Is there a documented monitoring plan? (Provide documentation of monitoring plan)
   a. If yes, continue to #5
   b. If no, clinical review required
   c. N/A, continue to #5

5. Is the requested treatment being prescribed by or in consultation with a specialist (i.e. gastroenterologist, hepatologist, infectious disease), or an ECHO participant?  
   *Note: If member has decompensated cirrhosis [Child-Turcotte-Pugh (CTP) class B or C], treatment must be prescribed by specialist*
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is this medication appropriate considering comorbid conditions or contraindications for use (e.g. renal function, pregnancy, malignancy outside of the liver not meeting oncologic criteria for cure, etc)? (Provide documentation of comorbid conditions)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is information with expected survival from non-hepatitis C associated morbidity 1 year or greater provided?  
   (Provide documentation of expected survival)
   a. If yes, continue to #8
   b. If no, clinical review required

8. Does the requested regimen match one of the approved regimens below or is it supported by current AASLD-IDSA guidelines with an evidence rating of Class I, Level B and higher? (Provide documentation of treatment regimen)
   a. If yes, approve for appropriate duration
   b. If no, clinical review required

### REGIMENS

<table>
<thead>
<tr>
<th>Treatment History</th>
<th>Cirrhosis status</th>
<th>Recommended Regimen</th>
</tr>
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<tbody>
<tr>
<td>Treatment-naïve or treatment-experienced with P/R</td>
<td>No cirrhosis</td>
<td>G/P x 8 weeks</td>
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<td></td>
<td></td>
<td>SOF/VEL x 12 weeks</td>
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<td>Treatment-experienced with NS3 protease inhibitor + P/R</td>
<td>Compensated cirrhosis</td>
<td>G/P x 12 weeks</td>
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<td>SOF/VEL x 12 weeks</td>
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<td>With or without compensated</td>
<td>G/P x 12 weeks</td>
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<td>(without NS5a inhibitor)</td>
<td>cirrhosis</td>
<td>SOF/VEL x 12 weeks</td>
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<td>With or without compensated</td>
<td>G/P x 12 weeks</td>
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<td>cirrhosis</td>
<td>SOF/VEL x 12 weeks</td>
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<td>With or without compensated</td>
<td>SOF/VEL/VOX x 12 weeks – GT1b</td>
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Last Reviewed: 9/19/2018
Effective Date: 1/1/2019
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<tr>
<th>Characteristics</th>
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<tbody>
<tr>
<td><strong>GENOTYPE 1</strong></td>
<td></td>
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<tr>
<td>Treatment-naive</td>
<td>G/P x 8 weeks</td>
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<td>Treatment-experienced</td>
<td>SOF/VEL x 12 weeks</td>
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<tr>
<td>Treatment-experienced with P/R</td>
<td>SOF/VEL x 12 weeks</td>
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<tr>
<td>Treatment-experienced with NS5a inhibitor</td>
<td>SOF/VEL/VOX x 12 weeks</td>
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<tr>
<td><strong>GENOTYPE 2</strong></td>
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<tr>
<td>Treatment-naive or treatment-experienced with P/R</td>
<td>G/P x 8 weeks</td>
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<tr>
<td>Treatment-experienced with SOF-containing regimen (without NS5a inhibitor)</td>
<td>G/P x 12 weeks</td>
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<td>G/P x 12 weeks</td>
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<tr>
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<td>G/P x 8 weeks</td>
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<td>G/P x 12 weeks</td>
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<tr>
<td>Treatment-experienced with NS5a inhibitors</td>
<td>G/P x 12 weeks</td>
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<tr>
<td><strong>GENOTYPE 4, 5, or 6</strong></td>
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<tr>
<td>Treatment-naive or treatment-experienced with P/R</td>
<td>G/P x 8 weeks</td>
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<td>Treatment-experienced with NS5a inhibitor</td>
<td>G/P x 12 weeks</td>
</tr>
</tbody>
</table>

*Baseline RAS testing for Y93H is recommended. If the Y93H substitution is identified, a different regimen should be used, or weight-based ribavirin should be added as an alternative option.

**UNIQUE POPULATIONS**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Recommended Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>DECOMPENSATED CIRRHOSIS: GENOTYPE 1, 2, 3, 4, 5, or 6</td>
<td></td>
</tr>
<tr>
<td>RBV eligible</td>
<td>SOF/VEL + RBV x 12 weeks</td>
</tr>
<tr>
<td>RBV ineligible</td>
<td>SOF/VEL x 24 weeks</td>
</tr>
<tr>
<td>Treatment-experienced with SOF or NS5a inhibitor</td>
<td>SOF/VEL + RBV x 24 weeks</td>
</tr>
<tr>
<td>POST LIVER TRANSPLANT: GENOTYPE 1, 4, 5, or 6 in the allograft</td>
<td></td>
</tr>
<tr>
<td>Treatment-naive or experienced no cirrhosis</td>
<td>G/P x 12 weeks</td>
</tr>
<tr>
<td>Treatment-naive or experienced with compensated or decompensated cirrhosis</td>
<td>LED/SOF + RBV x 12 weeks</td>
</tr>
<tr>
<td>POST LIVER TRANSPLANT: GENOTYPE 2 or 3 in the allograft</td>
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</tr>
<tr>
<td>Treatment-naive or experienced no cirrhosis</td>
<td>G/P x 12 weeks</td>
</tr>
<tr>
<td>Treatment-naive or experienced with compensated cirrhosis</td>
<td>SOF + DAC + RBV x 12 weeks</td>
</tr>
<tr>
<td>Treatment-naïve or experienced with decompensated cirrhosis</td>
<td>SOF/VEL + RBV x 12 weeks</td>
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<td>------------------------------------------------------------</td>
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<td></td>
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</tr>
</tbody>
</table>

^a low initial dose of ribavirin (600 mg) is recommended for patients with CTP class C cirrhosis
^b only available data for GT6 are in patients with compensated cirrhosis

**Note:**

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**References:**

Hereditary Angioedema Agents Policy
Prior Authorization Guidelines

Affected Medication(s)
- Berinert (human c1-esterase inhibitor) intravenous solution
- Cinryze (human c1-esterase inhibitor) intravenous solution
- Firazyr (icatibant acetate) subcutaneous solution
- Haegarda (human c1-esterase inhibitor) subcutaneous solution
- Ruconest (c1-esterase inhibitor recombinant) intravenous solution
- Takhzyro (lanadelumab-flyo) subcutaneous solution

Indication(s)
- **Berinert**: Treatment of acute abdominal, facial, or laryngeal hereditary angioedema (HAE) attacks in adult and pediatric patients
- **Cinryze**: Routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients (6 years old and above) with Hereditary Angioedema (HAE)
- **Firazyr**: Treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older
- **Haegarda**: Routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients
- **Ruconest**: Treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE)
- **Takhzyro**: Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older

Dosing
- **Berinert**: 20 IU/kg intravenously
- **Cinryze**:
  - Adults and adolescents 12 years and older: 1,000 U IV every 3 or 4 days
    - For inadequate response: Dose may be increased every 3 or 4 days up to 2,500 U (not to exceed 100U/kg)
  - Pediatric patients 6 to 11 years old: 500 U IV every 3 or 4 days
    - Dose may be adjusted according to individual response up to 1,000 U every 3 or 4 days
- **Firazyr**: 30 mg subcutaneously for attack, additional doses may be administered at intervals of at least 6 hours if attack persists or symptoms recur
- **Haegarda**: Self-administer 60IU/kg body weight subcutaneously twice weekly
- **Ruconest**:
  - For members weighing <84 kg: 50 U/kg intravenously
  - For members weighing ≥84 kg: 4200 U (2 vials) intravenously
  - No more than two doses should be administered within a 24 hour period
- **Takhzyro**:
  - 300mg subcutaneously every two weeks. Consider dosing every 4 weeks when patient is attack free for greater than 6 months
Initial Authorization Criteria

1. Is the request for continuation of the therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is the member avoiding possible triggers for HAE attacks? Possible triggers include:
   - Helicobacter pylori infections (confirmed by lab test)
   - Systemic estrogen products
   - Antihypertensive agents containing ACE inhibitors
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have at least 2 HAE attacks per month at baseline? (Provide supporting documentation for review)
   a. If yes, continue to #6
   b. If no, continue to #5

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 for review)
   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
- 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. For requests for Takhzyro or Cinryze, has the member had a trial with inadequate response, intolerance, or contraindication to therapy with Haegarda? (Provide supporting documentation)
   a. If yes, continue to #8
   b. If no, clinical review required

8. 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 criteria above?
   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 of improvement in severity or duration of attacks)
   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:

Affected Medication(s)

- Hetlioz oral capsule

FDA Approved Indication(s)

- For the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)

Dosing

- 20 mg by mouth taken before bedtime at the same time every night

Initial Authorization Criteria

1. Is the request for continuation of Hetlioz (tasimelteon) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have documentation of a minimum trial of 12 weeks of melatonin with insufficient response, an intolerance, or contraindication to therapy with melatonin? (Provide relevant current/past medication history)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member completely blind with no light perception? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the treatment being prescribed by or in consult with a specialist specialized in sleep disorders?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member had a positive clinical response to therapy as defined as decreased symptoms? (Provide supporting documentation)
   a. If yes, continue to #3
b. If no, clinical review required

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

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References:
Impavido® (miltefosine)
Prior Authorization Guidelines

Affected Medication(s)

- Impavido oral capsule

FDA Approved Indication(s)

- In adults and adolescents ≥12 years of age weighing ≥ 30 kg for treatment of:
  - Visceral leishmaniasis caused by *Leishmania donovani*
  - Cutaneous leishmaniasis caused by *Leishmania braziliensis, Leishmania guyanensis,* and *Leishmania panamensis*
  - Mucosal leishmaniasis caused by *Leishmania braziliensis*

Dosing

- Patients weighing 30 to 44 kg: 50 mg twice daily with food for 28 days
- Patients weighing 45 kg or greater: 50 mg three times daily with food for 28 days

Authorization Criteria

1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, continue to #2

2. Does the member currently have a free-living ameba infection? (Examples include primary amebic meningoencephalitis (PAM) due to *Naegleria fowleri* and granulomatous amebic encephalitis (GAE) due to *Balamuthia mandrillaris* and *Acanthamoeba spp.*). (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the member at least 12 years of age and weighs at least 30 kg? (Provide member weight for review)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the treatment being prescribed by, or in consultation with, an infectious disease specialist?
   a. If yes, approve for 1 month
   b. If no, clinical review required

Note:

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References:

1. Impavido (prescribing information). Paladin Therapeutics Inc. Wilmington, DE. March 2014.


### Affected Medication(s)

- Increlex subcutaneous 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 request for continuation of Increlex (mecasermin) therapy?
   a. If yes, continue to **Reauthorization**
   b. If no, continue to #2

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

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

4. Does the member have any of the following secondary forms of IGF-1 deficiency?
   - 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 #5

5. Is the medication being prescribed by, or in consultation with, a pediatric endocrinologist?
   a. If yes, continue to #6
   b. If no, clinical review required

6. What diagnosis is Increlex being requested for?
   a. Severe IGF-1 deficiency, continue to corresponding criteria
   b. Growth hormone (GH) gene deletion, continue to corresponding criteria
Severe IGF-1 Deficiency

1. Does the member have a height standard deviation score of less than or equal to -3.0? (Provide documentation of height standard deviation score for review)
   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 documentation of basal IGF-1 standard deviation score for review)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have normal or elevated growth hormone levels? (Provide documentation of growth hormone level for review)
   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 documentation of basal IGF-1 level for review)
   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 of neutralizing antibodies)
   a. If yes, approve for 12 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 documentation of diagnosis)
   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 documentation of height velocity for review)
   a. If yes, continue to #3
   b. If no, clinical review required

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

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**References:**

## Affected Medication(s)

- Abilify Maintena (aripiprazole) IM injection
- Aristada (aripiprazole lauroxil) IM injection
- Geodon (ziprasidone mesylate) IM injection
- Invega Sustenna (paliperidone palmitate) IM injection
- Invega Trinza (paliperidone palmitate) IM injection
- Risperdal Consta (risperidone) IM injection
- Haloperidol decanoate IM injection
- Haldol (haloperidol decanoate) IM injection
- Haloperidol lactate injection solution
- Haldol (haloperidol lactate) injection solution
- Olanzapine IM injection
- Zyprexa (olanzapine) IM injection
- Zyprexa Relprevv (olanzapine) IM injection

## FDA Approved Indication(s)

- **Abilify Maintena**: For the treatment of schizophrenia in adults and as maintenance monotherapy treatment of bipolar I disorder in adults
- **Aristada**: For the treatment of schizophrenia
- **Geodon**: For the treatment of acute agitation in schizophrenic patients
- **Invega Sustenna**: For the treatment of schizophrenia in adults and for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants
- **Invega Trinza**: For the treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna (1-month paliperidone palmitate extended-release injectable suspension) for at least four months
- **Risperdal Consta**: For the treatment of schizophrenia and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder
- **Haldol**: For the treatment of schizophrenia and the control of tics and vocal utterances of Tourette's Disorder
- **Haldol decanoate**: For the treatment of schizophrenic patients who require prolonged parenteral antipsychotic therapy.
- **Olanzapine injection**: For the treatment of acute agitation associated with schizophrenia and bipolar I mania
- **Zyprexa injection**: For the treatment of schizophrenia, the acute treatment of manic or mixed episodes associated with bipolar I disorder and maintenance treatment of bipolar I disorder, and the treatment of acute agitation associated with schizophrenia and bipolar I mania
  - **In combination with fluoxetine**: For the treatment of depressive episodes associated with bipolar I disorder and the treatment of treatment resistant depression (major depressive disorder in patients who do not respond to 2 separate trials of different antidepressants of adequate dose and duration in the current episode)
- **Zyprexa Relprevv**: For the treatment of schizophrenia

## Dosing

- Refer to corresponding package insert for specific dosing recommendations
Initial Authorization Criteria

1. Is the request for continuation of therapy with an injectable antipsychotic?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is the request for a long acting injectable medication?
   a. If yes, continue to #4
   b. If no, approve for 6 months unless otherwise specified

4. Is medical rationale provided why the member cannot use an oral antipsychotic medication? (Provide supporting documentation including medical rationale)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the request for Abilify Maintena, Aristada, Haldol Deconate, Risperdal Consta, invega Sustenna, or invega Trinza? (Provide documentation of treatment regimen)
   a. Yes, continue to #6
   b. If no, approve for 6 months unless otherwise specified

6. Has the member previously trialed the oral antipsychotic formulation of the selected product to ensure tolerability? (Provide documentation of oral formulation trial)
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member experienced a positive clinical response to therapy defined as controlled disease? (Provide supporting documentation of controlled psychiatric symptoms)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

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

References:

10. Zyprexa Relprevv (olanzapine) [package insert]. Indianapolis, IN; Eli Lilly and Company; February 2018.
## Idiopathic Pulmonary Fibrosis (IPF) agents
### Prior Authorization Guidelines

**Affected Medication(s)**
- Esbriet (pirfenidone) oral capsule/tablet
- Ofev (nintedanib) oral capsule

**FDA Approved Indication(s)**
- For the treatment of idiopathic pulmonary fibrosis (IPF)

**Dosing**
- Esbriet: 801 mg three times daily (refer to package insert for titration recommendations)
- Ofev: 150 mg twice daily

### Initial Authorization Criteria

1. Is the request for continuation of Esbriet (pirfenidone) or Ofev (nintedanib) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

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

3. Is documentation confirming diagnosis of idiopathic pulmonary fibrosis (IPF) including presence of usual interstitial pneumonia (UIP), high resolution computed tomography (HRCT) result, or surgical lung biopsy result provided? (Provide supporting documentation for review)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. Does the member have a Forced Vital Capacity (FVC) of $\geq 50\%$ of predicted or a carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) $30\%$ or greater of predicted? (Provide FVC and/or DLCO test result for review)
   - a. If yes, continue to #5
   - b. If no, clinical review required

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

### Reauthorization Criteria

1. Is the request to treat an FDA approved indication? (Provide documentation of diagnosis)
   - a. If yes, continue to #2
   - b. If no, clinical review required
2. Does the member demonstrate a positive clinical response to therapy as defined by a reduction in disease progression? (Provide FVC test result and supportive documentation)
   c. If yes, continue to #3
d. If no, clinical review required

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

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References:
# Juxtapid® (lomitapide mesylate) Prior Authorization Guidelines

## Affected Medication(s)
- Juxtapid oral capsule

## FDA Approved Indication(s)
- Indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)

## Dosing
- Initially 5mg orally once daily
- Refer to package insert for dose titration chart

## Initial Authorization Criteria

1. Is the request for continuation of Juxtapid (lomitapide) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is the diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) supported by one of the following? (Provide supporting documentation)
   - Treated LDL-C $\geq$ 300 mg/dL or non-HDL-C $\geq$ 330 mg/dL
   - Untreated LDL-C $\geq$ 500 mg/dL AND with one of the following (i or ii):
     i. Tendinous or cutaneous xanthoma prior to age 10 years;
     ii. Evidence of HeFH in both parents (e.g., documented history of elevated LDL-C $\geq$ 190 mg/dL prior to lipid-lowering therapy)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member 18 years of age or older?
   a. If yes, continue to #5
   b. If no, clinical review required

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

6. Has the member been on high-intensity statin therapy for the last 3 consecutive months and will continue with high-intensity statin therapy? High-intensity statin therapy includes: atorvastatin 40-80 mg or rosuvastatin 20-40 mg (Document current statin regimen with initiation date and verify adherence)
  a. If yes, continue to #11
  b. If no, continue to #7

7. What is the rationale provided for avoiding high-intensity statin therapy? (Provide supporting documentation for review)
  a. Statin intolerance due to myalgia or myopathy, continue to #8
  b. History of rhabdomyolysis with creatinine kinase (CK) levels greater than 10-times upper limit of normal (document date occurred) OR labeled contraindication to all statin therapy, continue to #10
  c. All other rationale, clinical review required

8. Is the member currently receiving a maximally tolerated dose of a statin AND ezetimibe and will continue statin and ezetimibe with the requested medication?
  a. If yes, continue to #11
  b. If no, continue to #9

9. Is documentation of persistent myalgia or myopathy on 2 separate 8 week trials with pravastatin, rosuvastatin, or fluvastatin provided?
  a. If yes, continue to #10
  b. If no, clinical review required

10. Has the member been on ezetimibe for 3 consecutive months and will continue with the requested medication?
    a. If yes, continue to #11
    b. If no, clinical review required

11. Does the member have a documented trial with insufficient response, intolerance, or contraindication to a PCSK9 inhibitor (Examples: Repatha or Praluent)? (Provide supporting documentation)
    a. If yes, continue to #12
    b. If no, clinical review required

12. Is the medication being prescribed by or in consultation with cardiologist, endocrinologist, or lipid specialist?
    a. If yes, approve for 6 months, unless otherwise specified
    b. If no, clinical review required

**Reauthorization Criteria**

1. Is the requested medication being used for an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the diagnosis of Homozygous Familial Hypercholesterolemia confirmed by one of the following? (Provide supporting documentation)
   - Treated LDL-C ≥ 300 mg/dL or non-HDL-C ≥ 330 mg/dL
   - Untreated LDL-C ≥ 500 mg/dL, AND with one of the following (i or ii):
     i. Tendinous or cutaneous xanthoma prior to age 10 years;
     ii. Evidence of HeFH in both parents (e.g., documented history of elevated LDL-C ≥ 190 mg/dL prior to lipid-lowering therapy)

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

3. Has the member demonstrated a positive clinical response to therapy? (Provide documentation of an LDL-C reduction since the initiation of therapy)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is an updated lipid panel result received? (Provide lipid panel results for review)
   a. If yes, continue to #5
   b. If no, clinical review required

5. 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:
   https://doi.org/10.1161/CIRCULATIONAHA.114.013189.

college of endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. 
Endocrine Practice April 2017; 23(4): 479-497. Available at: https://doi.org/10.4158/EP171764.GL
### Affected Medication(s)

- Jynarque oral tablet

### FDA Approved Indication(s)

- To slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

### Dosing

- Initially: 60 mg orally per day as 45 mg taken on waking and 15 mg taken 8 hours later
- Titrate to 90 mg taken on waking and 30 mg taken 8 hours later if tolerated
- Refer to package insert for dose adjustments for patients taking moderate CYP 3A inhibitors

### Initial Authorization Criteria

1. Is the request for continuation of Jynarque (tolvaptan) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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 diagnosis of autosomal dominant polycystic kidney disease confirmed by ultrasonography, MRI/CT scan, or genetic testing? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required

5. 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 #6
   b. If no, clinical review required
6. 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, uncorrected abnormal blood sodium concentrations, unable to sense or respond to thirst, hypovolemia, uncorrected urinary outflow obstruction, or anuria)
   a. If yes, clinical review required
   b. If no, continue to #7
7. Does the member have baseline liver function (ALT and AST) and bilirubin levels within normal range? (Provide documentation of AST, ALT and bilirubin levels taken within the previous 3 months for review)
   a. If yes, continue to #8
   b. If no, clinical review required
8. 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. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. 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 of positive clinical response)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Has the member experienced an increase in ALT, AST, or bilirubin to greater than 2 times the upper limit of normal? (Provide updated ALT, AST, and bilirubin levels for review)
   a. If yes, clinical review required
   b. If no, continue to #4
4. 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:
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References:


**Affected Medication(s)**

- Kalydeco oral tablet
- Kalydeco oral granules

**FDA Approved Indication(s)**

- Treatment of cystic fibrosis (CF) in patients age 12 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 12 months-6 years:
  - 7 kg to less than 14 kg: One 50 mg packet twice daily with fat-containing food
  - 14 kg or greater: One 75 mg packet twice daily with fat-containing food

**Initial Authorization Criteria**

1. Is the request for continuation of Kalydeco® (ivacaftor) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is there documentation that the member has a cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation that is responsive to ivacaftor based on in vitro data and/or clinical data? (Provide documentation of specific mutation for review)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is there documentation of the member’s pulmonary status (baseline FEV1) and liver function (ALT and AST) and are the liver enzymes within normal limits? (Provide documentation of pulmonary and liver tests for review)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the member at least 12 months of age?
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is Kalydeco® (ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received? (Provide documentation of improvement of FEV1 from baseline and/or a reduction in the number of pulmonary exacerbations)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Has documentation been provided of liver function tests (ALT and AST) within the last year and are they within normal limits? (Provide ALT and AST levels for review)
   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?
   a. If yes, approve for 12 months unless otherwise
   b. If no, clinical review required

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References:


Keveyis® (dichlorphenamide)
Prior Authorization Guidelines

Affected Medication(s)
- Keveyis oral tablet

FDA Approved Indication(s)
- Treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants

Dosing
- Initially: 50 mg twice daily
- Titrate as needed based on response with maximum dose of 200 mg per day

Initial Authorization Criteria

1. Is the request for continuation of Keveyis (dichlorphenamide) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Are both baseline serum potassium and bicarbonate levels received? (Provide supporting labs for review)
   a. If yes, continue to #4
   b. If no, clinical review required

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

5. Is the treatment being prescribed by, or in consultation with, a neurologist?
   a. If yes, continue to #6
   b. If no, clinical review required

6. What diagnosis is the medication being requested for?
   a. Hypokalemic periodic paralysis, continue to corresponding criteria
   b. Hyperkalemic periodic paralysis, continue to corresponding criteria

Hypokalemic periodic paralysis

1. Does the member have a history of two or more attacks of muscle weakness with documented serum potassium <3.5 mEq/L? (Provide supporting documentation of attacks with muscle weakness and serum potassium levels for review)
a. If yes, continue to #4
b. If no, continue to #2

2. Does the member have a history of one attack of muscle weakness and one attack of weakness in one family relative with documented serum potassium <3.5 mEq/L? (Provide supporting documentation of members’ and their family relatives’ attack with muscle weakness and serum potassium levels for review)
   a. If yes, continue to #4
   b. If no, continue to #3

3. Does the member have three or more of the following six clinical/laboratory features?
   - Onset in the first or second decade of life (childhood or teenage years)
   - Duration of attack (muscle weakness involving ≥1 limbs) longer than two hours
   - The presence of triggers (previous carbohydrate rich meal, symptom onset during rest after exercise, stress)
   - Improvement in symptoms with potassium intake
   - A family history of the condition or genetically confirmed skeletal calcium or sodium channel mutation
   - Positive long exercise test
   a. If yes, continue to #4
   b. If no, clinical review required

4. Have other causes of hypokalemia been ruled out? (i.e. renal, adrenal, thyroid dysfunction; renal tubular acidosis; diuretic and laxative abuse)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Have dietary interventions been trialed with inadequate response? (Provide documentation of high potassium intake and low sodium intake)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Has the member been taking and will continue to take a potassium supplement throughout therapy? (Provide supporting documentation)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Hyperkalemic periodic paralysis

1. Has the member’s diagnosis been confirmed by electromyography, genetic testing, or provocative testing? (Provide supporting documentation of testing done to confirm diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member had an ECG performed to exclude prolonged QT and/or ventricular arrhythmias? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Have other causes of hyperkalemia been ruled out? (i.e. Andersen-Tawil syndrome, adrenal insufficiency, renal dysfunction, or drug abuse)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Have dietary and exercise restrictions been trialed with inadequate response? (Provide documentation of low potassium intake and exercise restrictions)
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member had a positive clinical response to therapy as defined by a decrease in the frequency in paralytic attacks? (Provide supporting documentation for review)
   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 unless otherwise specified
   b. If no, clinical review required

Note:
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References:
Korlym® (mifepristone)
Prior Authorization Guidelines

**Affected Medication(s)**
- Korlym oral tablet

**FDA Approved Indication(s)**
- To control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing’s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery

**Dosing**
- 300 mg orally once daily

**Initial Authorization Criteria**

1. Is the request for continuation of Korlym (mifepristone) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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. Is the member a female of reproductive age?
   a. If yes, continue to #5
   b. If no, continue to #6

5. Has pregnancy been excluded by a negative pregnancy test and will the member use contraception while on therapy? (Provide supporting documentation of negative pregnancy test and contraception use)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the member have endogenous hypercortisolism? (i.e. not hypercortisolism due to chronic high dose glucocorticoids) (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Does the member have type 2 diabetes or glucose intolerance secondary to hypercortisolism confirmed by HbA1c? (Provide supporting documentation including current HbA1c)
   a. If yes, continue to #8
   b. If no, clinical review required
8. Has the member failed surgery or is the member not a surgical candidate? (Trans-sphenoidal surgery for pituitary dependent Cushing’s or surgical removal of an adrenocortical tumor in malignant Cushing’s) (Provide supporting documentation of surgery or rationale for avoiding surgery)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Does the member have a trial with inadequate response or an intolerance to steroidogenesis inhibitor? (i.e. ketoconazole, Metyrapone)
   a. If yes, continue to #10
   b. If no, clinical review required

10. Does the member have a trial with inadequate response, an intolerance, or contraindication to treatment with maximum dose of metformin? Note: If patient has GI discomfort, metformin ER (Glucophage XR) should be trialed (Provide documentation of trial, intolerance, or contraindication)
    a. If yes, continue to #11
    b. If no, clinical review required

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

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<th>Reauthorization Criteria</th>
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<td>1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)</td>
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<td>a. If yes, continue to #2</td>
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<td>b. If no, clinical review required</td>
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<tr>
<td>2. Is the member a female of reproductive age?</td>
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<td>a. If yes, continue to #3</td>
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<td>b. If no, continue to #6</td>
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<td>3. Have more than 14 days passed between the last dose and the next scheduled dose? (Provide documentation of date of last dose and date of next scheduled dose)</td>
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<td>a. If yes, continue to #4</td>
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<td>b. If no, continue to #5</td>
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<tr>
<td>4. Has pregnancy been excluded by a negative pregnancy test? (Provide documentation of date of last dose and negative pregnancy test if indicated)</td>
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<td>a. If yes, continue to #5</td>
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<td>b. If no, clinical review required</td>
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<td>5. Does the member use contraception while on therapy? (Provide documentation of contraception use)</td>
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<td>a. If yes, continue to #6</td>
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<td>b. If no, clinical review required</td>
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</tbody>
</table>
6. Has the member had a positive clinical response to therapy as defined by improved glucose control? (Provide supporting documentation including an updated HbA1c)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the treatment 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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References:
**Affected Medication(s)**

- Kuvan powder for oral solution
- Kuvan oral tablet, disintegrating

**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 request for continuation of Kuvan (sapropterin dihydrochloride) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

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

3. 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 #4
   - b. If no, clinical review required

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

5. Will the member have a phenylalanine blood level measured after 1 week of therapy and then periodically for up to 2 months of therapy?
   - a. If yes, continue to #6
   - b. If no, clinical review required

6. 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 documentation of diagnosis)**
   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 pretreatment and updated phenylalanine levels)**
   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?**
   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:

# Kynamro® ( mipomersen sodium)  
## Prior Authorization Guidelines

**Affected Medication(s)**

- Kynamro subcutaneous solution

**FDA Approved Indication(s)**

- Indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)

**Dosing**

- 200 mg subcutaneously once weekly

## Initial Authorization Criteria

1. Is the request for continuation of Kynamro (mipomersen) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is the diagnosis of Homozygous Familial Hypercholesterolemia supported by one of the following? (Provide supporting documentation)
   * Treated LDL-C ≥ 300 mg/dL or non-HDL-C ≥ 330 mg/dL
   * Untreated LDL-C ≥ 500 mg/dL AND with one of the following (i or ii):
     i. Tendinous or cutaneous xanthoma prior to age 10 years;  
     ii. Evidence of HeFH in both parents (e.g., documented history of elevated LDL-C ≥ 190 mg/dL prior to lipid-lowering therapy)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member 18 years of age or older?
   a. If yes, continue to #5
   b. If no, clinical review required

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

6. Has the member been on high-intensity statin therapy for the last 3 consecutive months and will continue with high-intensity statin therapy? High-intensity statin therapy includes: atorvastatin 40-80 mg or rosuvastatin 20-40 mg (Document current statin regimen with initiation date and verify adherence)
   a. If yes, continue to #11
   b. If no, continue to #7

7. What is the rationale provided for avoiding high-intensity statin therapy? (Provide supporting documentation for review)
   a. Statin intolerance due to myalgia or myopathy, continue to #8
   b. History of rhabdomyolysis with creatinine kinase (CK) levels greater than 10-times upper limit of normal (document date occurred) OR labeled contraindication to all statin therapy, continue to #10
   c. All other rationale, clinical review required

8. Is the member currently receiving a maximally tolerated dose of a statin AND ezetimibe and will continue statin and ezetimibe with the requested medication?
   a. If yes, continue to #11
   b. If no, continue to #9

9. Is documentation of persistent myalgia or myopathy on 2 separate 8 week trials with pravastatin, rosuvastatin, or fluvastatin provided?
   a. If yes, continue to #10
   b. If no, clinical review required

10. Has the member been on ezetimibe for consecutive 3 months and will continue with the requested medication?
    a. If yes, continue to #11
    b. If no, clinical review required

11. Does the member have a documented trial with insufficient response, intolerance, or contraindication to a PCSK9 inhibitor (i.e. Repatha or Praluent)? (Provide supporting documentation)
    a. If yes, continue to #12
    b. If no, clinical review required

12. Is LDL apheresis part of the lipid lowering regimen?
    a. If yes, clinical review required
    b. If no, continue to #13

13. Is the medication being prescribed by or in consultation with cardiologist, endocrinologist, or lipid specialist?
    a. If yes, approve for 6 months, unless otherwise specified
    b. If no, clinical review required
## Reauthorization Criteria

1. **Is the requested medication being used for an FDA approved indication? (Provide documentation of diagnosis)**
   
   a. If yes, continue to #2
   
   b. If no, clinical review required

2. **Is the diagnosis of Homozygous Familial Hypercholesterolemia supported by one of the following? (provide supporting documentation)**
   
   
   - Treated LDL-C ≥ 300 mg/dL or non-HDL-C ≥ 330 mg/dL
   
   - Untreated LDL-C ≥ 500 mg/dL AND with one of the following (i or ii):
     
     i. Tendinous or cutaneous xanthoma prior to age 10 years;
     
     ii. Evidence of HeFH in both parents (e.g., documented history of elevated LDL-C ≥ 190 mg/dL prior to lipid-lowering therapy)

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

3. **Is there documentation of a positive clinical response to therapy? (Provide documentation of an LDL-C reduction since the initiation of therapy)**

   a. If yes, continue to #4
   
   b. If no, clinical review required

4. **Is an updated lipid panel result received? (Provide lipid panel results for review)**

   a. If yes, continue to #5
   
   b. If no, clinical review required

5. **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

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### References:


Affected Medication(s)

- Leukine for subcutaneous injection

FDA Approved Indication(s)

- In adult patients with cancer undergoing autologous hematopoietic stem cell transplantation for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis
- To increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])
- To shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML)
- For the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric patients 2 years of age and older with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's lymphoma (HL)
- For the acceleration of myeloid reconstitution in adult and pediatric patients 2 years of age and older undergoing allogeneic bone marrow transplantation from HLA-matched related donors
- For the treatment of adult and pediatric patients 2 years and older who have undergone allogeneic or autologous bone marrow transplantation in whom neutrophil recovery is delayed or failed

Dosing

- Refer to package insert for specific dosing recommendations

Authorization Criteria

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

2. Is Leukine (sargramostim) being requested for one of the following FDA approved indications? (For intravenous administration request, contact medical benefit administer for coverage)
   - Peripheral Blood Progenitor Cell (PBPC) mobilization, collection, or transplantation
   - Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome [H-ARS])

   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a documented trial with insufficient response, intolerance, or contraindication to myeloid growth factors (Examples: Zarxio, Neupogen, etc)? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the treatment being prescribed by or in consultation with an oncologist, hematologist, or a transplant specialist?
   a. If yes, approve for 3 months unless otherwise specified
   b. If no, clinical review required

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References:
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) sargramostim. 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.
## Affected Medication(s)
- Lucemyra oral tablet

## FDA Approved Indication(s)
- For mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults

## Dosing
- Recommended starting dose: is 0.54 mg 4 times daily during the period of peak withdrawal symptoms
- Continue for up to 14 days
- Gradual dose reduction over 2-4 day period

## Authorization Criteria

1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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, continue to #3
   b. If no, clinical review required

3. Was the therapy with Lucemyra (lofexidine) been initiated at the inpatient setting?
   a. If yes, approve for 14 days
   b. If no, continue to #4

4. Is there medical rationale why an opioid taper cannot be used? (Examples of opioid taper medications include: buprenorphine, methadone, other opioids)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Has the member had a trial with inadequate response, intolerance, or contraindication to clonidine?
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the medication being prescribed by, or in consultation with, a provider specializing in pain management, or addiction medicine?
   a. If yes, approve for 14 days
   b. If no, clinical review required

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### Authorization Criteria

1. **Is the requested medication being used for an FDA approved or major compendia supported indication?** (Verify regimen and dosing)
   - a. If yes, continue to #2
   - b. If no, clinical review required

2. **Is the request supported by current medical guidelines?**
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. **Did the member exhaust all formulary alternative products for treatment of the requested condition?** (Provide supporting documentation)
   - a. If yes, approve for lesser of 12 months OR standard treatment duration
   - b. If no, clinical review required

**Note:**

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

### FDA Approved Indication(s)
- Prophylactic agent to reduce the incidence of ifosfamide-induced hemorrhagic cystitis

### Dosing
- Two oral doses after bolus IV injection
- Oral doses of 40% of the ifosfamide dose at 2 and 6 hours after ifosfamide administration
- Repeat on each day ifosfamide is administered

### Authorization Criteria

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

2. Is the member currently receiving or planning to receive ifosfamide containing chemotherapy regimen? (Provide supporting documentation)
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. Is the member’s body surface area and treatment plan provided for review of appropriate dosing? (Provide BSA and treatment plan for review)
   - a. If yes, continue to #4
   - b. If no, clinical review required

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

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### References:
### Affected Medication(s)

- Methyltestosterone oral capsule
- Android oral capsule
- Methitest oral tablet
- Testred oral capsule

### FDA Approved Indication(s)

- In males:
  - Primary hypogonadism (congenital or acquired)
  - Hypogonadotropic hypogonadism (congenital or acquired)
  - To stimulate puberty in carefully selected males with clearly delayed puberty
- In females:
  - may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal

### Dosing

- In males: initial dosage of 10-50 mg daily
- In females: 50-200 mg daily

### Initial Authorization Criteria

1. Is the request for continuation of therapy with the same methyltestosterone product?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. What is the diagnosis that the methyltestosterone product is being requested for?
   a. Male member with delayed puberty, continue to corresponding criteria
   b. Male member with hypogonadism, continue to corresponding criteria
   c. Female member with metastatic/inoperable breast cancer, clinical review required
   d. Gender identity disorder, continue to corresponding therapy

#### Male member with delayed puberty

1. Is the member 12 years of age or older?
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member have Tanner Staging of IV or below?
   a. If yes, approve for 6 months unless otherwise specified
b. If no, clinical review required

**Male member with hypogonadism**

1. Does the member have documentation of TWO baseline total testosterone levels < 300 ng/dL that were taken in the morning on different days? (Provide documentation of total testosterone levels)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have at least TWO signs/symptoms of hypogonadism? (e.g. sleep disturbances, gynecomastia, decreased lean body mass, visceral obesity, hot flashes, changes in mood) (Provide supporting documentation of signs/symptoms)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is there medical rationale why the member cannot use a generic injectable AND topical testosterone product? (Provide supporting documentation)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

**Gender Dysphoria**

1. Does the member have a diagnosis of gender identity disorder 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, continue to #3
   b. If no, clinical review required

3. 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, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have documentation of a positive clinical response to therapy defined by one of the following? (Provide supporting documentation)
   - For members with delayed puberty, documentation of progression into puberty AND with Tanner Staging of IV or less
   - For members with hypogonadism, documentation of normal testosterone levels

Last Reviewed: 12/19/18
Effective Date: 1/1/19
- For members with gender dysphoria, documentation of achieving expected therapy outcome
  a. If yes, approve for 12 months unless otherwise specified
  b. If no, clinical review required

**Note:**
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**References:**
Mircera® (methoxy polyethylene glycol-epoetin beta)  
Prior Authorization Guidelines

Affected Medication(s)
- Mircera injection solution

FDA Approved Indication(s)
- Treatment of anemia associated with chronic kidney disease (CKD) in adult patients on dialysis and patients not on dialysis

Dosing
- Recommended starting dose for patients who are not currently treated with an ESA: 0.6 mcg/kg administered as a single IV or SC injection once every two weeks
- Refer to package insert for specific dose titration recommendations
- Once hemoglobin stabilized, may be administered once monthly

Initial Authorization Criteria
1. Is the request for continuation of Mircera (methoxy polyethylene glycol-epoetin beta) therapy in which the last dose was received less than 60 days ago? (Provide documentation of date of last administration)
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is the requested medication planning to be administered through subcutaneous route? (For intravenous routes of administration request, contact medical benefit provider)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the member on hemodialysis? (Note: IV administration is preferred for members on hemodialysis due to lower immunogenicity)
   a. If yes, clinical review required
   b. If no, continue to #5
5. Does the member have a hemoglobin (hb) level less than 10 g/dL and/or hematocrit (Hct) less than 30%? (Provide documentation of hemoglobin and hematocrit lab values taken within 30 days prior to planned administration)
   a. If yes, continue to #6
   b. If no, clinical review required
6. Does the member have adequate iron stores as defined by serum ferritin $\geq 100$ ng/mL and transferrin saturation (TSAT) $\geq 20\%$? (Provide documentation of serum ferritin and transferrin saturation levels taken within 30 days of planned administration)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Have other causes of anemia been ruled out such as hemolysis, bleeding, vitamin deficiency, etc? (Provide supporting documentation)
   a. If yes, approve for 45 days unless otherwise specified
   b. If no, clinical review required

**Reauthorization Criteria**

1. Is the request for use to treat an FDA approved indication) and the last dose was less than 60 days ago? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member had a positive clinical response to therapy as defined by a stabilization in hemoglobin and/or a reduction in the need for RBC transfusion? (Provide documentation of stabilization of hemoglobin or reduction in the need for RBC transfusions)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have a hemoglobin (hb) level less than 11 g/dL and/or hematocrit (hct) less than 33%? (Provide documentation of hemoglobin and hematocrit lab values taken within 30 days prior to planned administration)
   a. If yes, continue to #5
   b. If no, continue to #4

4. Does the member have a hemoglobin (hb) level between 11 and 12 g/dL and will the Mircera dose be interrupted or reduced to the lowest dose sufficient to reduce the need for RBC transfusions? (Provide documentation of hemoglobin lab values taken within 30 days prior to planned administration and documentation of plan to interrupt therapy or reduce dose)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have adequate iron stores as defined by serum ferritin $\geq 100$ ng/mL and transferrin saturation (TSAT) $\geq 20\%$? (Provide documentation of serum ferritin and transferrin saturation levels taken within 30 days of planned administration)
   a. If yes, approve for 45 days unless otherwise specified
   b. If no, clinical review required

**Note:**

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

References:


Affected Medication(s)

- Avonex (interferon beta-1a)
- Aubagio (teriflunomide)
- Betaseron (interferon beta-1b)
- Extavia (interferon beta-1b)
- Gilenya (fingolimod)
- Copaxone (glatiramer acetate)
- Plegridy (interferon beta-1a)
- Rebif (interferon beta-1a)
- Tecfidera (dimethyl fumarate)

FDA Approved Indication(s)

- For treatment of patients with relapsing forms of multiple sclerosis:
  Avonex, Aubagio, Betaseron, Extavia, Copaxone, Plegridy, Rebif, Tecfidera
- For treatment of patients (10 years of age and older) with relapsing forms of multiple sclerosis:
  Gilenya

Dosing

- **Avonex**: 30 mcg IM injection once a week
- **Aubagio**: 7 mg or 14 mg orally once daily
- **Betaseron**: 0.25 mg SC injection every other day
- **Extavia**: 0.25 mg SC injection every other day
- **Gilenya**: 0.25 mg to 0.5 mg orally once daily
- **Copaxone**: 20 mg SC injection daily OR 40 mg SC injection three times weekly
- **Plegridy**: 125 mcg subcutaneous injection every 14 days
- **Rebif**: 22 mcg or 44 mcg SC injection three times per week
- **Tecfidera**: 240 mg orally once daily

Initial Authorization Criteria

1. Is the request for continuation of a multiple sclerosis agent therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is an MRI result consistent with multiple sclerosis received? (Provide MRI for review)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the requested medication one of the following: Avonex, Glatiramer acetate, or Tecfidera?
   a. If yes, continue to #9
b. If no, continue to #5

5. Is Gilenya being requested?
   a. If yes, continue to #6
   b. If no, continue to #8

6. Does the member have history of inadequate response, intolerance, OR contraindication to ONE of the following agents: Avonex, Glatiramer acetate, or Tecfidera? (Provide documentation of treatment history, intolerance, or contraindication to therapy)
   a. If yes, continue to #9
   b. If no, continue to #7

7. Is Gilenya being requested to be used in a pediatric member?
   a. If yes, continue to #9
   b. If no, clinical review required

8. Does the member have history of inadequate response, intolerance, OR contraindication to TWO of the following agents: Avonex, Glatiramer acetate, or Tecfidera? (Provide documentation of treatment history, intolerance, or contraindication to therapy)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Will the requested medication be used with other disease-modifying therapy for multiple sclerosis?
   a. If yes, clinical review required
   b. If no, continue to #10

10. Is the requested multiple sclerosis agent being prescribed by or in consultation with a neurologist?
    a. If yes, approve for 12 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Will the requested medication be used with other disease-modifying therapy for multiple sclerosis?
   a. If yes, clinical review required
   b. If no, continue to #3

3. Is clinical documentation confirming responsiveness to therapy provided (Provide documentation of disease stability)
   a. If yes, continue to #4
   b. If no, clinical review required
4. Is the requested multiple sclerosis agent being prescribed by or in consultation with a neurologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:
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References:
**Affected Medication(s)**

- Myalept powder for subcutaneous injection

**FDA Approved Indication(s)**

- As an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy

**Dosing**

- Refer to package insert for recommended doses based on gender and weight

**Initial Authorization Criteria**

1. Is the request for continuation of Myalept (metreleptin) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have at least one of the following complications associated with leptin deficiency in patients with congenital or acquired generalized lipodystrophy? (Provide supporting documentation)
   - Diabetes mellitus
   - Hypertriglyceridemia
   - Increased fasting insulin levels
   a. If yes, continue to #4
   b. If no, clinical review required

4. Have baseline HbA1c, fasting glucose, and fasting triglycerides levels been received? (Provide labs for review)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have documentation of a trial with insufficient response to at least one conventional medication to treat each metabolic complication present? (Examples: metformin, sulfonylureas, pioglitazone, or insulin for diabetes, and gemfibrozil, fenofibrate, or statins for hypertriglyceridemia)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the requested medication being used for any of the following conditions? (Provide clinical documentation for review)
   - Partial lipodystrophy
   - HIV-related lipodystrophy
- Metabolic disease without concurrent evidence of congenital or acquired generalized lipodystrophy
  
  a. If yes, clinical review required
  b. If no, continue to #7

7. Is the treatment being prescribed by, or in consultation with an endocrinologist?
  
  a. If yes, approve for 6 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 documentation of diagnosis)
   
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member demonstrated a positive clinical response to therapy as defined by improvement in at least one metabolic parameter? (Provide documentation and updated HbA1c, fasting glucose, an fasting triglycerides level for review)
   
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the treatment 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

**Note:**

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**References:**


## Affected Medication(s)

- Fulphila (pegfilgrastim-jmdb) subcutaneous solution
- Granix (tbo-filgrastim) injection solution
- Neulasta (pegfilgrastim) subcutaneous solution
- Neupogen (filgrastim) injection solution
- Zarxio (filgrastim-sndz) injection solution

## FDA Approved Indication(s)

- To reduce the duration of severe neutropenia in adult and pediatric patients 1 month and older with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia
  - Granix
- 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
  - Fulphila, Neulasta
- 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
  - Neupogen, Zarxio
- 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)
  - Neupogen, Zarxio
- 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
  - Neupogen, Zarxio
- For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
  - Neupogen, Zarxio
- 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
  - Neupogen, Zarxio
- To increase survival in patients acutely exposed to myelosuppressive doses of radiation
  - Neulasta, Neupogen

## Dosing

- Refer to package insert for recommended dosing for corresponding diagnosis

## Authorization Criteria

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

2. Is Neupogen (filgrastim-sndz) being requested?
   a. If yes, continue to #3
   b. If no, continue to #5

3. Does the member have a documented trial with inadequate response or intolerance to Zarxio? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, continue to #4

4. Is Neupogen being requested for a member with hematopoietic radiation injury syndrome?
   a. If yes, approve for 4 month unless otherwise specified
   b. If no, clinical review required

5. Is Granix being requested?
   a. If yes, continue to #6
   b. If no, continue to #7

6. Does the member have a documented trial with inadequate response or intolerance to Zarxio? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the medication being prescribed by or in consultation with an oncologist/hematologist or an appropriate specialist?
   a. If yes, continue to #8
   b. If no, clinical review required

8. What is the medication being requested for? (Provide clinical documentation to support diagnosis)
   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. Acute exposure to myelosuppressive doses of radiation, approve for 4 months unless otherwise specified
   e. Prophylaxis of febrile neutropenia in patients with non-myeloid malignancy, continue to corresponding criteria
   f. Treatment of chemotherapy-induced febrile neutropenia, continue to corresponding criteria
   g. Severe Chronic Neutropenia, continue to corresponding criteria
   h. 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?
   a. If yes, continue to #2
   b. If no, continue to #4

2. Is the planned chemotherapy regimen for curative treatment intent?
   a. If yes, approve for 4 months unless otherwise specified
   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, approve for 4 months unless otherwise specified
   b. If no, clinical review required

4. 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 #5
   b. If no, continue to #6

5. Does the planned chemotherapy regimen have an intermediate risk (10 to 20% risk) of febrile neutropenia?
   a. If yes, continue to #7
   b. If no, clinical review required

6. Is the member continuing the same chemotherapy regimen which induced a dose-limiting neutropenic event on a previous cycle? (Provide supporting clinical documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the planned chemotherapy regimen for curative treatment intent?
   a. If yes, approve for 4 months unless otherwise specified
   b. If no, clinical review required

Treatment of chemotherapy-induced febrile neutropenia

1. Has the member received a prophylaxis regimen for febrile neutropenia with a granulocyte colony stimulating factor on the current chemotherapy cycle?
   a. If yes, clinical review required
   b. If no, continue to #2
2. Does the member have an absolute neutrophil count (ANC) <500/mm³? (Provide documentation of ANC lab value)
   a. If yes, continue to #3
   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 CBC with differential for review)
   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 documentation of diagnosis)
   - 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 documentation of symptoms)
   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? (Examples: Micromedex, Clinical Pharmacology, NCCN, etc) (Provide supporting documentation confirming diagnosis)
   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 all prior treatment history, contraindication if appropriate, and treatment plan)
   a. If yes, approve for 4 months unless otherwise specified
   b. If no, clinical review required

**Note:**

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**References:**

9. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) filgrastim. 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.


Mytesi® (crofelemer)
Prior Authorization Guidelines

Affected Medication(s)
- Mytesi delayed-release oral tablet

FDA Approved Indication(s)
- For symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy

Dosing
- 125 mg taken orally twice daily

Initial Authorization Criteria
1. Is the request for continuation of Mytesi (crofelemer) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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. Is the member currently on anti-retroviral therapy and with non-infectious diarrhea for longer than one month? (Provide list of relevant current medications and supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Does the member have a trial with insufficient response, intolerance, or contraindication to one of the following alternative anti-diarrheal medications: loperamide, bismuth subsalicylate, or diphenoxylate/atropine? (Provide relevant past medication history and/or intolerance/contraindication)
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
2. Does the member demonstrate a positive clinical response to therapy as defined as a decrease in the frequency and/or severity of diarrhea? (Provide supporting documentation)
a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

Note:
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References:
Natpara® (parathyroid hormone)
Prior Authorization Guidelines

Affected Medication(s)
- Natpara powder for subcutaneous solution

FDA Approved Indication(s)
- As an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism

Dosing
- Refer to package insert for recommended dosing based on total serum calcium and 24-hour urinary calcium excretion

Initial Authorization Criteria

1. Is the request for continuation of Natpara (parathyroid hormone) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is the member diagnosed with hypocalcemia due to chronic hypoparathyroidism (i.e. not acute post-surgical hypoparathyroidism)?
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the cause of hypoparathyroidism due to calcium-sensing receptor mutations?
   a. If yes, clinical review required
   b. If no, continue to #5

5. Has the member been adherent to minimum 1,000 mg of elemental calcium and 400 IU of vitamin D supplementation daily for a minimum of 6 months and unable to maintain normal serum-albumin corrected calcium? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Will the member continue calcium and vitamin D supplementation concurrently with Natpara?
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the members’ serum albumin corrected calcium greater than 7.5 mg/dL? (Please provide lab values within the past 30 days)
   a. If yes, continue to #8
   b. If no, clinical review required
8. Is the member’s serum 25-hydroxyvitamin D ≥ 30 ng/mL (75nmol/L)? (Please provide lab values within the past 30 days)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Is the treatment being prescribed by, or in consultation with, an endocrinologist?
   a. If yes, continue to #9
   b. If no, clinical review required

### Reauthorization Criteria

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

2. Has the member continued to take daily calcium and vitamin D supplementation concurrently with Natpara?
   a. If yes, continue to #3
   b. If no, clinical review required

3. Are the member’s serum calcium levels regularly monitored and appropriate dosage adjustments made to meet the patient specific therapeutic goal? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member demonstrate a positive clinical response to therapy as defined by one of the following: (Provide labs results for review)
   - Serum calcium level 8-9 mg/dL within the last 90 days
   - Serum calcium level >9 mg/dL within the last 90 days, and Natpara dose is being decreased
   a. If yes, continue to #5
   b. If no, clinical review required

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

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**References:**

**Affected Medication(s)**

- Northera oral capsule

**FDA Approved Indication(s)**

- Treatment of orthostatic dizziness, lightheadedness, or the “feeling that you are about to black out” in adult patients with symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (Parkinson's disease [PD], multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy

**Dosing**

- Starting dose: 100 mg, taken orally three times daily
- Titrate to symptomatic response, in increments of 100 mg three times daily every 24 to 48 hours up to a maximum dose of 600 mg three times daily

**Initial Authorization Criteria**

1. Is the request for continuation of Northera (droxidopa) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have documentation of primary autonomic failure (by Parkinson's disease [PD], multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is there documentation that the member has tried at least TWO non-pharmacological interventions to treat the conditions as outlined below? (Provide supporting documentation of non-pharmacological interventions tried)
   i. Elevation of the bed by 5-20 degrees
   ii. Use of compression stockings
   iii. Increased salt and water intake
   iv. Avoidance of precipitating factors including arising too quickly, alcohol consumption, hot baths, or hot environments
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have a sufficient trial with inadequate response, intolerance, or contraindication to both midodrine AND fludocortisone? (Provide documentation of trials, intolerances, or contraindications)
   a. If yes, continue to #6
6. Is the treatment being prescribed by, or in consultation with, a neurologist?
   a. If yes, approve for 2 weeks
   b. If no, clinical review required

Reauthorization Criteria

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

2. Did the member have a positive clinical response to therapy as defined as less frequent episodes of orthostatic dizziness, lightheadedness, or the “feeling that you are about to black out”? (Provide supporting documentation of less frequent symptomatic episodes)
   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, continue to #4
   b. If no, clinical review required

4. Is clinical rationale provided for continued use beyond 2 weeks? (Provide supporting documentation)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

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References:

# Nuplazid® (pimavanserin tartrate)
## Prior Authorization Guidelines

### Affected Medication(s)
- Nuplazid oral capsule
- Nuplazid oral tablet

### FDA Approved Indication(s)
- Treatment of hallucinations and delusions associated with Parkinson's disease psychosis

### Dosing
- 34 mg orally once daily

### Initial Authorization Criteria

1. Is the request for continuation of Nuplazid (pimavanserin tartrate) therapy?
   a. If yes, continue to **Reauthorization**
   b. If no, continue to #2

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

3. Have the member’s hallucinations or delusions developed after the onset of Parkinson’s disease? (Provide documentation of onset of hallucinations or delusions in relation to onset of Parkinson’s Disease)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Was an attempt made to reduce doses or discontinue medications that may contribute to, or cause, hallucinations and/or delusions or has rationale for no dose reduction/discontinuation been received? (Examples of medications include: dopamine agonists, amantadine, monoamine oxidase B inhibitors, and anticholinergics) (Provide documentation of attempted dose reduction, discontinuation, or rationale for avoidance)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the treatment being prescribed by, or in consultation with, a neurologist?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
b. If no, clinical review required

2. Has the member experienced a positive clinical response to therapy as defined by a reduction in the frequency and/or severity of hallucinations or delusions? (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 unless otherwise specified
   b. If no, clinical review required

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**References:**


Ocaliva® (obeticholic acid)
Prior Authorization Guidelines

**Affected Medication(s)**

- Ocaliva® oral tablet

**FDA Approved Indication(s)**

- For the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA/ursodiol) in adults with an inadequate response to UDCA/ursodiol, or as monotherapy in adults unable to tolerate UDCA

**Dosing**

- Refer to package insert for specific dosing and titration based on Child-Pugh Class

**Initial Authorization Criteria**

1. Is the request for continuation of Ocaliva (obeticholic acid) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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 trial with insufficient response defined as greater than ALP 1.67x ULN or total bilirubin greater than 1x ULN but less than 2x ULN with at least 12 months of ursodiol at a dose of ≥ 13 mg/kg/day? (Provide relevant medication history and response to therapy)
   a. If yes, continue to #6
   b. If no, continue to #5

5. Does the member have an intolerance or contraindication to ursodiol? (Provide supporting documentation of intolerance or contraindication)
   a. If yes, continue to #7
   b. If no, clinical review required

6. Will the member be using Ocaliva in combination with ursodiol? (Provide treatment plan)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the treatment being prescribed by, or in consultation with, a hepatologist or gastrointestinal (GI) specialist?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required
## Reauthorization Criteria

<table>
<thead>
<tr>
<th>Step</th>
<th>Criteria</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)</td>
<td>a. If yes, continue to #2</td>
</tr>
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<td></td>
<td></td>
<td>b. If no, clinical review required</td>
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<tr>
<td></td>
<td>2. Is the member 18 years of age or older?</td>
<td>a. If yes, continue to #3</td>
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<td></td>
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<td>b. If no, clinical review required</td>
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<td></td>
<td>3. Is the member having a positive clinical response to therapy as defined by a maintained reduction in alkaline phosphate (ALP) level from pretreatment level? (Provide updated ALP levels for review)</td>
<td>a. If yes, continue to #4</td>
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<td>b. If no, clinical review required</td>
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<tr>
<td></td>
<td>4. Is the treatment being prescribed by, or in consultation with, a hepatologist or gastrointestinal (GEI) specialist?</td>
<td>a. If yes, approve for 12 months unless otherwise specified</td>
</tr>
<tr>
<td></td>
<td></td>
<td>b. If no, clinical review required</td>
</tr>
</tbody>
</table>

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### References:


Oncology Agents
Prior Authorization Guidelines

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<tr>
<th>Affected Medication(s)</th>
<th>Affected Medication(s)</th>
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<tbody>
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<td>• Alkeran (melphalan oral tablet)</td>
<td>• Nexavar (sorafenib tosylate tablet)</td>
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<td>• Sylatron (peginterferon alfa-2b subcutaneous powder for solution)</td>
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<td>• Synribo (omacetaxine mepesuccinate subcutaneous solution)</td>
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<td>• Erivedge (vismodegib capsule)</td>
<td>• Tabloid (thioguanine tablet)</td>
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<td>• Tafinlar (dabrafenib mesylate capsule)</td>
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<td>• etoposide capsule</td>
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<td>• Fareston (toremifene citrate tablet)</td>
<td>• Tarceva (erlotinib hydrochloride tablet)</td>
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<td>• Farydak (panobinostat capsule)</td>
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<td>• Gleostine (lomustine capsule)</td>
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<td>• Gleevec (imatinib tablet)</td>
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<td>• Hexalen (altretamine capsule)</td>
<td>• Trexstar (triptorelin pamoate powder for IM injection)</td>
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<td>• Hycamtin (topotecan capsule)</td>
<td>• Tykerb (lapatinib ditosylate tablet)</td>
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<td>• Ibrance (palbociclib capsule)</td>
<td>• Valchlo (mechlorethamine hydrochloride topical gel)</td>
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<td>• Iclusig (ponatinib hydrochloride tablet)</td>
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<td>• Yonsa (abiraterone acetate tablet)</td>
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<td>• Lenvima (lenvatinib capsule)</td>
<td>• Zelboraf (vemurafenib tablet)</td>
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<td>• Leukeran (chlorambucil tablet)</td>
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<td>• Lynparza (olaparib tablet and capsule)</td>
<td>• Zykdia (ceritinib capsule)</td>
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<tr>
<td>• Matulane (procarcabazine capsule)</td>
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<tr>
<td>• Mekinist (trametinib dimethyl sulfoxide tablet)</td>
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</tbody>
</table>
• Myleran (busulfan tablet)
• Nerlynx (neratinib tablet)
• Zytiga (abiraterone acetate tablet)

Indication(s)
• Refer to major compendia for supported use

Dosing:
• Refer to indication specific compendia supported dosing

Initial Authorization Criteria

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

2. Is the medication being requested to be used for an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #4
   b. If no, continue to #3

3. Is the medication being requested being used for an indication supported by the National Comprehensive Cancer Network (NCCN) 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 #4
   b. If no, clinical review required

4. 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 #5
   b. If no, clinical review required

5. Is the medication being prescribed by or in consultation with an oncologist?
   a. If yes, approve for 4 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Is the documented indication approved by the FDA or supported by the NCCN recommendation with an evidence level of 2A or higher? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is there clinical documentation confirming disease responsiveness to therapy provided? (Examples include reduction in tumor size, objective response, delay in progression, partial response, etc.) (Provide supporting documentation)
   a. If yes, continue to #2
   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 month unless otherwise specified
   b. If no, clinical review required

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References:
Opioid Induced Constipation Agents  
Prior Authorization Guidelines

**Affected Medication(s)**

- Relistor (methylnaltrexone) oral tablet
- Relistor (methylnaltrexone) subcutaneous solution
- Movantik (naloxegol) oral tablet
- Symproic (naldemedine) oral tablet

**FDA Approved Indication(s)**

- For the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation
  - Relistor oral tablet, Movantik, Symproic
- For the treatment of OIC in adult patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care
  - Relistor subcutaneous solution

**Dosing**

- Refer to appropriate package insert for dosing recommendations

**Initial Authorization Criteria**

1. Is the request for continuation of therapy with the same opioid-induced constipation agent?  
   a. If yes, continue to Reauthorization  
   b. If no, continue to #2

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

3. Does the member have a clinical diagnosis of opioid-induced constipation (OIC) as defined as the following? (Provide supporting documentation)
   - < 3 spontaneous bowl movements (SBM) per week AND
   - 25% of SBMs associated with one or more of the following:
     - Straining
     - hard or lumpy stools
     - sensation of incomplete evacuation
   a. If yes, continue to #4
   b. If no, clinical review required

4. Has the member been taking opioids for at least 4 weeks duration? (Provide supporting documentation)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Is the member taking opioids for non-cancer pain or pain associated with a prior cancer?
   a. If yes, continue to #7
   b. If no and request is for Relistor (methylnaltrexone) subcutaneous solution, continue to #6
   c. If no and request is for Movantik (naloxegol), Symproic (naldemedine), or Relistor (methylnaltrexone) oral tablet clinical review required

6. Is the member taking opioids due to advanced illness requiring palliative care? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Has the member tried laxatives (e.g. psyllium, methylcellulose) AND at least one of the following categories for a minimum of 2 weeks (administered on a regular schedule, not PRN) and had inadequate response? (Provide documentation of medications trialed with response)
   - Stool softener (e.g. docusate)
   - Osmotic laxative (e.g. polyethylene glycol, lactulose, magnesium citrate)
   - Stimulant laxative (e.g. senna, bisacodyl)
   - Lubricant (e.g. mineral oil)
   a. If yes, continue to #8
   b. If no, clinical review required

8. Will another opioid antagonist be coadministered with the requested medication?
   a. If yes, clinical review required
   b. If no, continue to #9

9. Does the member have known or suspected gastrointestinal obstruction or is at increased risk of recurrent obstruction?
   a. If yes, clinical review required
   b. If no and request is for Relistor (methylnaltrexone), continue to #10
   c. If no and request is for Movantik (naloxegol) or Symproic (naldemedine), approve for 6 months unless otherwise specified

10. Has the member tried preferred agents, Movantik (naloxegol) or Symproic (naldemedine), with inadequate response or has a contraindication to use of either? (Provide supporting documentation)
    a. If yes, approve for 4 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member still on chronic opioid therapy that is per the FDA-approved indications? (Provide supporting documentation)
   a. If yes, continue to #3
b. If no, clinical review required

3. What medication is being requested?
   a. Movantik or Symproic, continue to #6
   b. Relistor, continue to #4

4. Is the indication for OIC associated with advanced illness? (Provide supporting documentation)
   a. If yes, clinical review required
   b. If no, continue to #5

5. Is the indication for OIC associated with chronic non-cancer pain? (Provide supporting documentation)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Has beneficial response to requested medication (i.e. increased number of bowl movements from baseline) been documented by the prescriber? (Provide supporting documentation)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:
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References:

2. Movantik (naloxegol) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals, LP; 2018
Affected Medication(s)

- Abstral sublingual tablet
- Actiq mucous membrane lozenge/troche (fentanyl lozenge on a handle)
- Fentora buccal tablet
- Lazanda nasal spray
- Subsys sublingual spray

Indication(s)

- **Abstral**: Management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain
- **Actiq**: Management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain
- **Fentora**: Management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain
- **Lazanda**: Management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain
- **Subsys**: Management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain

Dosing

- Refer to corresponding package insert for dosing recommendations

Initial Authorization Criteria

1. Is the request for renewal of a previously approved oral or nasal fentanyl product prior authorization with the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member meet the appropriate age for the FDA approved use of the medication? (At least 16 years of age for Actig and at least 18 years of age for all others)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member’s cancer pain inadequately controlled despite adherence to around the clock opioid therapy? (Provide documentation of current medication regimen and inadequately controlled pain)
   a. If yes, continue to #5
   b. If no, clinical review required
5. Does the member have a trial with inadequate response to at least TWO other oral or parenteral short-acting narcotic products that are used for breakthrough pain in cancer patients? (examples: morphine, hydromorphone, and oxymorphone)? (Provide documentation of medications tried and inadequate response)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Is the member considered opioid tolerant defined as those who are taking at least: 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equivalent dose of another opioid for a week or longer? (Provide documentation of opioid tolerance)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the medication being prescribed by, or in consult with, an oncologist or palliative care provider?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Does the member continue to meet criteria for initial authorization as outlined above?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member demonstrate a positive clinical response to therapy as documented by a greater control of break-through pain? (Provide supporting documentation)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:
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References:
**Orfadin®, Nityr® (nitisinone)
Prior Authorization Guidelines**

### Affected Medication(s)
- Orfadin (nitisinone) oral capsule
- Nityr (nitisinone) oral tablet

### Indication(s)
- For the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine

### Dosing:
- 0.5 mg/kg orally twice daily, maximum dose of 2 mg/kg daily

### Initial Authorization Criteria

1. Is the request for continuation of nitisinone therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

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

3. Is documentation confirming diagnosis of hereditary tyrosinemia type 1 provided? (Provide documentation of biochemical testing, clinical presentation, and/or DNA testing result)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. Is baseline urine or plasma succinylacetone level provided? (Provide baseline urine or plasma succinylacetone level for review)
   - a. If yes, continue to #5
   - b. If no, clinical review required

5. Is documentation of adherence to nutritional therapy provided? (Provide supporting documentation of restriction of tyrosine and phenylalanine adherence)
   - a. If yes, continue to #6
   - b. If no, clinical review required

6. Is the member’s current weight provided? (Provide members weight for review)
   - a. If yes, continue to #7
   - b. If no, re-route to technician for provider outreach

7. Is the request for Orfadin (nitisinone)?
8. Does the member have an intolerance to Nityr (nitisinone) or is clinical rationale supporting inability to take Nityr provided? (Provide supporting documentation of intolerance or clinical rationale)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Is the treatment being prescribed by, or in consultation with, a provider that is specialized in treatment of hereditary tyrosinemia or related disorders?
   a. If yes, approve for 4 months unless otherwise specified
   b. If no, clinical review required

### Reauthorization Criteria

1. Is nitisinone being requested for an FDA approved or major compendia supported indication?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is documentation of adherence to nutritional therapy received? (Provide supporting documentation of restriction of tyrosine and phenylalanine adherence)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Has documentation of significant clinical response to therapy been provided? (Provide supporting documentation of complete urine or plasma succinylacetaone suppression confirmed by lab result)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is member’s current weight provided? (Provide member’s weight for review)
   a. If yes, continue to #5
   b. If no, re-route to technician for provider outreach

5. Is the treatment being prescribed by or in consultation with a provider that is specialized in treatment of hereditary tyrosinemia or related disorders?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

### Note:

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References:

Orkambi® (lumacaftor/ivacaftor)
Prior Authorization Guidelines

Affected Medication(s)

- Orkambi oral tablet
- Orkambi oral granules

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 request for continuation of Orkambi® (lumacaftor/ivacaftor) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is there documentation that the member has the homozygous F508del mutation by a FDA-cleared CF mutation test? (Provide report for review)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Has documentation of pulmonary function (baseline FEV1) and liver function (ALT and AST) been provided and are the liver enzymes within normal range? (Provide documentation of pulmonary and liver tests for review)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the member at least 2 years of age?
   a. If yes, continue to #6
   b. If no, clinical review required
6. Is Orkambi® (lumacaftor/ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis member?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Were updated chart notes (within past year) provided with documentation of clinical response to prior therapy received? (Provide documentation of improvement of FEV1 from baseline and/or a reduction in the number of pulmonary exacerbations)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Has documentation been provided of liver function tests (ALT and AST) within the last year and are they within normal limits? (Provide ALT and AST levels for review)
   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 member?
   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)

- Oxandrin oral tablet
- Oxandrolone oral tablet

### FDA Approved Indication(s)

- Adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, and to offset the protein catabolism associated with prolonged administration of corticosteroids
- For the relief of the bone pain frequently accompanying osteoporosis

### Dosing

- For adults: 2.5 mg to 20 mg given in 2 to 4 divided doses
- For children: total daily dosage is ≤0.1 mg per kilogram body weight or ≤0.045 mg per pound of body weight
- For geriatric: 5 mg twice daily

### Initial Authorization Criteria

1. Is the request for continuation of Oxandrin (oxandrolone) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   - a. If yes, continue to #3
   - b. If no, continue to #9

3. Is the request for Oxandrin?
   - a. If yes, continue to #4
   - b. If no, continue to #5

4. Does the member have a trial with inadequate response to generic oxandrolone or is medical rationale provided why the member cannot take the generic oxandrolone? (Provide documentation of trial with inadequate response or medical rationale for avoiding therapy with oxandolone)
   - a. If yes, continue to #5
   - b. If no, clinical review required

5. Is the medication being requested for bone pain due to osteoporosis?
   - a. If yes, clinical review required
   - b. If no, continue to #6

6. Is the medication being requested to promote weight gain due to failure to gain or to maintain normal weight?
   - a. If yes, continue to #7
   - b. If no, continue to #8
7. Does the member have a trial with inadequate response, intolerance, or contraindication to taking nutritional supplements? (Provide supporting documentation)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

8. Is the medication being requested for protein catabolism associated with chronic corticosteroid administration? (Provide documentation of chronic corticosteroid administration)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

9. Is the requested use supported by major compendia?
   a. If yes, continue to #10
   b. If no, clinical review required

10. Is the request for Oxandrin (oxandrolone)?
    a. If yes, continue to #11
    b. If no, approve for 6 months unless otherwise specified

11. Does the member have a trial with inadequate response to generic oxandrolone or is medical rationale provided why the member cannot take the generic oxandrolone? (Provide documentation of trial with inadequate response or medical rationale for avoiding therapy with oxandrolone)
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Reauthorization Criteria

1. Is the request for use to treat an FDA approved indication or supported by major compendia? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Has the member demonstrated a positive clinical response to therapy defined as an improvement in weight gain, an increase in lean body mass, decreased bone pain, etc.? 
   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)

- Adcirca (tadalafil) oral tablet
- Adempas (riociguat) oral tablet
- Letairis (ambrisentan) oral tablet
- Opsumit (macitentan) oral tablet
- Orenitram ER (treprostinil) oral tablet
- Revatio (sildenafil) oral tablet
- Revatio (sildenafil) oral powder for suspension
- Sildenafil oral tablet (20 mg tablet only)
- Tadalafil oral tablet (20 mg tablet only)
- Tracleer (bosentan) oral tablet
- Tracleer (bosentan) oral tablet for suspension
- Uptravi (selexipag) oral tablet

FDA Approved Indication(s)

- **Adcirca**
  - Treatment of pulmonary arterial hypertension (PAH, WHO Group 1) to improve exercise ability

- **Adempas**
  - Treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH, WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class
  - Treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1), to improve exercise capacity, WHO functional class and to delay clinical worsening

- **Letairis**
  - Treatment of pulmonary arterial hypertension (PAH, WHO Group 1):
    - To improve exercise ability and delay clinical worsening
    - In combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability

- **Opsumit**
  - Treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risk of disease progression and hospitalization for PAH

- **Orenitram ER**
  - Treatment of pulmonary arterial hypertension (PAH, WHO Group 1) to improve exercise capacity

- **Revatio**
  - Treatment of pulmonary arterial hypertension (PAH, WHO Group 1) in adults to improve exercise ability and delay clinical worsening

- **Tracleer**
  - Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1):
    - In adults to improve exercise ability and to decrease clinical worsening
    - In pediatric patients ages 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability

- **Uptravi**
  - Treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH
**Dosing**

- Refer to corresponding package insert for specific dosing recommendations

**Initial Authorization Criteria**

1. Is the request for continuation of therapy with the same oral pulmonary arterial hypertension agent?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is the request for use to treat PAH World Health Organization (WHO) Group 1? (Provide documentation of PAH, WHO Group 1)
   a. If yes, continue to #5
   b. If no, continue to #4

4. Is the request for use to treat persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4? (Provide documentation of CTEPH WHO Group 4)
   a. If yes, continue to corresponding criteria
   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 by 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? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the prescriber a relevant specialist (i.e. pulmonologist or cardiologist)?
   a. If yes, continue to criteria corresponding to diagnosis and requested agent
   b. If no, clinical review required

**Chronic Thromboembolic Pulmonary Hypertension**

1. Has the diagnosis been confirmed by ventilation/perfusion (V/Q) scan, right heart catheterization demonstrating mPAP ≥ 25 mmHg and PCWP ≤15 mmHg, and presumed to be caused by thromboembolic occlusion of the pulmonary vasculature? (Provide supporting documentation)
   a. If yes, continue to #2
2. Is the member 18 years of age or older?
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the member status post pulmonary thromboendarterectomy, status post balloon pulmonary angioplasty, ineligible for surgery, or bridging definitive surgery? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the request for a female member with reproductive potential?
   a. If yes, continue to #5
   b. If no, continue to #6

5. 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 #6
   b. If no, clinical review required

6. Will Adempas (riociguat) be used concomitantly with a PDE5 inhibitor or other organic nitrate?
   a. If yes, clinical review required
   b. If no, continue to #7

7. Is the medication being prescribed by, or in consultation with an appropriate specialist (i.e. pulmonologist or cardiologist)?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

PAH, Phosphodiesterase-5 Enzyme (PDE5) Inhibitors: Adcirca (tadalafil), tadalaflil, Revatio (sildenafil), sildenafil

1. Does the member currently take other organic nitrates in any form, regularly or intermittently? (Examples include isosorbide dinatirate, isosorbide mononitrate, and nitroglycerin) (Provide medication list for review)
   a. If yes, clinical review required
   b. If no, continue to #2

2. Will the requested PDE5 inhibitor be used concomitantly with Adempas (riociguat)? (Provide documentation of treatment plan)
   a. If yes, clinical review required
   b. If no, continue to #3

3. Is the request for sildenafil?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, continue to #4

4. Is the request for Adcirca (tadalafil) or Revatio (sildenafil)?
<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Is there documentation to support inadequate response or inability to tolerate sildenafil? (Provide documentation of inadequate response or intolerance)</td>
</tr>
<tr>
<td></td>
<td>a. If yes, approve for 6 months unless otherwise specified</td>
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<tr>
<td></td>
<td>b. If no, clinical review required</td>
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<tr>
<td>6.</td>
<td>If request is for Revatio (sildenafil) suspension?</td>
</tr>
<tr>
<td></td>
<td>a. If yes, continue to #7</td>
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<td></td>
<td>b. If no, clinical review required</td>
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<tr>
<td>7.</td>
<td>Is there documentation for why member is unable to take solid dosage form? (Provide documentation with rationale why the member is unable to take solid dosage form)</td>
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<tr>
<td></td>
<td>a. If yes, approve for 6 months unless otherwise specified</td>
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<tr>
<td></td>
<td>b. If no, clinical review required</td>
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</tbody>
</table>

**PAH, Endothelin Receptor Antagonists: Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Does the member have documentation of inadequate response, contraindication, or intolerance to a PDE5 inhibitor (e.g. sildenafil)? (Provide documentation of inadequate response, contraindication, or intolerance)</td>
</tr>
<tr>
<td></td>
<td>a. If yes, continue to #2</td>
</tr>
<tr>
<td></td>
<td>b. If no, clinical review required</td>
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<tr>
<td>2.</td>
<td>Is the member a female of reproductive potential?</td>
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<td></td>
<td>a. If yes, continue to #3</td>
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<tr>
<td></td>
<td>b. If no, continue to #4</td>
</tr>
<tr>
<td>3.</td>
<td>Has a pregnancy test been obtained within 30 days prior to start of treatment to exclude pregnancy? (Provide supporting documentation)</td>
</tr>
<tr>
<td></td>
<td>a. If yes, continue to #4</td>
</tr>
<tr>
<td></td>
<td>b. If no, clinical review required</td>
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<tr>
<td>4.</td>
<td>Does the member have preexisting moderate or severe hepatic impairment? (Provide documentation of hepatic status)</td>
</tr>
<tr>
<td></td>
<td>a. If yes, clinical review required</td>
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<td></td>
<td>b. If no, continue to #5</td>
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<tr>
<td>5.</td>
<td>Is the request for Letairis (ambrisentan) or Opsumit (macitentan)?</td>
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<tr>
<td></td>
<td>a. If yes, continue to #6</td>
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<tr>
<td></td>
<td>b. If no, continue to #7</td>
</tr>
<tr>
<td>6.</td>
<td>Is the member 18 years of age or older?</td>
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<tr>
<td></td>
<td>a. If yes, approve for 6 months unless otherwise specified</td>
</tr>
<tr>
<td></td>
<td>b. If no, clinical review required</td>
</tr>
</tbody>
</table>
| 7.   | Is the request for Tracleer (bosentan)?
a. If yes, continue to #8  
b. If no, clinical review required

8. Will Tracleer (bosentan) be used concurrently with cyclosporine or glyburide? (Provide documentation of medication list)  
a. If yes, clinical review required  
b. If no, approve for 6 months unless otherwise specified

PAH, Soluble Guanylate Cyclase Stimulator: Adempas (riociguat)

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 documentation of inadequate response, contraindication, or intolerance to a PDE5 inhibitor (e.g. sildenafil)? (Provide documentation of inadequate response, contraindication, or intolerance)  
a. If yes, continue to #3  
b. If no, clinical review required

3. Does the member have documentation of inadequate response, contraindication, or intolerance to an endothelin receptor antagonist (e.g. Tracleer, Opsumit, or Letairis)? (Provide documentation of inadequate response, contraindication, or intolerance)  
a. If yes, continue to #4  
b. If no, clinical review required

4. Is the member a female of reproductive potential?  
a. If yes, continue to #5  
b. If no, continue to #6

5. Has pregnancy test been obtained within 30 days prior to start of treatment to exclude pregnancy? (Provide supporting documentation)  
a. If yes, continue to #6  
b. If no, clinical review required

6. Will Adempas (riociguat) be used concomitantly with a PDE5 inhibitor or other organic nitrate? (Provide documentation of treatment plan)  
a. If yes, clinical review required  
b. If no, approve for 6 months unless otherwise specified

PAH, Prostanoids/Prostacyclins: Orenitram ER (treprostinil), Uptravi (selexipag)

1. Does the member have documentation of inadequate response, contraindication, or intolerance to at least two of the following: PDE5 inhibitor, endothelin receptor antagonist, or Adempas (riociguat)? (Provide documentation of inadequate response, contraindication, or intolerance)  
a. If yes, continue to #2  
b. If no, clinical review required
2. Will the member be taking the requested agent in combination with another prostanoid/prostacyclin (e.g. epoprostenol, iloprost)? (Provide documentation of treatment plan)
   a. If yes, clinical review required
   b. If no, continue to #3

3. Does the member have severe hepatic impairment (Child Pugh Class C)? (Provide supporting documentation of hepatic status)
   a. If yes, clinical review required
   b. If no, approve for 6 months unless otherwise specified

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**Reauthorization Criteria**

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

2. Does the member have 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 otherwise specified
   b. If no, clinical review required

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**Note:**

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**References:**


12. Letairis (ambrisentan) [package insert]. Foster City, CA: Gilead Sciences, Inc; 2015


Affected Medication(s)

- Palynziq (pegvaliase-pqpz) subcutaneous solution

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 request for continuation of Palynziq (pegvaliase-pqpz) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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 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 (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

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### Reauthorization Criteria

1. **Is the documented indication FDA approved or supported by major compendia? (Provide documentation of diagnosis)**
   - 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

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**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:**

# PCSK9 Inhibitors
## Prior Authorization Guidelines

### Affected Medication(s)

- Praluent subcutaneous solution
- Repatha subcutaneous solution

### FDA Approved Indication(s)

- **Praluent**
  - As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C

- **Repatha**
  - As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C
  - To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease
  - 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 to 150 mg every 2 weeks OR 300 mg once per month
- **Repatha**: 140 mg every 2 weeks OR 420 mg once per month

### Initial Authorization Criteria

1. **Is the request for continuation of PCSK9 therapy?**
   - a. If yes, continue to **Reauthorization**
   - b. If no, continue to #2

2. **Is the requested medication being used for an FDA-approved indication?**
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. **Is all of the following documentation 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 #4
     - b. If no, clinical review required

4. **What is the diagnosis that PCSK9 inhibitor is being requested for? (Provide documentation of diagnosis) Note: Praluent is only FDA approved for HeFH**
   - a. Heterozygous or Homozygous familial hypercholesterolemia (HeFH/HoFH), continue to #5
b. Hypercholesterolemia with history of clinical atherosclerotic cardiovascular disease (ASCVD), continue to #7

c. Other indication, continue to #9

5. 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?
   a. If yes, continue to #6
   b. If no, clinical review required

6. 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 #10
   b. If no, clinical review required

7. Is pre-treatment LDL-cholesterol received (within 3 months) with baseline LDL-C greater than 100 mg/dL?
   a. If yes, continue to #8
   b. If no, clinical review required

8. Does the member have atherosclerotic cardiovascular disease (ASCVD) confirmed by at least one of the following: (Provide documentation of past medical history)
   - 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 #10
   b. If no, clinical review required

9. Is pre-treatment LDL-cholesterol received (within 3 months) with baseline LDL-C greater than 130 mg/dL?
   a. If yes, continue to #10
   b. If no, clinical review required

10. Is the Member currently receiving high-intensity statin therapy for 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 (Document current statin regimen with initiation date)
    a. If yes, continue to #15
    b. If no, continue to #11
11. What is the rationale provided for avoiding high-intensity statin therapy? (Provide supporting documentation for avoidance)
   a. Statin intolerance due to myalgia or myopathy, continue to # 12
   b. History of rhabdomyolysis with creatinine kinase (CK) levels greater than 10-times upper limit of normal (document date occurred), continue to #14
   c. Labeled contraindication to all statins, continue to #14
   d. All other rationale, clinical review required

12. Is the member currently receiving a maximally tolerated dose of a statin AND ezetimibe and will continue statin and ezetimibe with PCSK9?
   a. If yes, continue to #15
   b. If no, continue to #13

13. Is documentation of persistent myalgia or myopathy on 2 separate 8 week trials with pravastatin, rosuvastatin, or fluvastatin provided? (Provide documentation of intolerance)
   a. If yes, continue to #14
   b. If no, clinical review required

14. Has the member been on ezetimibe for 3 consecutive months and will continue concurrently with PCSK9?
   a. If yes, continue to #15
   b. If no, clinical review required

15. 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

Reauthorization Criteria

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

2. Is updated lipid panel received with confirmation of significant reduction in LDL defined as a decrease in LDL levels of at least 40% from pre-treatment levels? (Provide updated lab results)
   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
Note:
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References:

Previews® (letermovir)
Prior Authorization Guidelines

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
<th>• Prevymis oral tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Approved Indication(s)</td>
<td>• Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)</td>
</tr>
<tr>
<td>Dosing</td>
<td>• 480 mg once daily through day 100 post-transplantation</td>
</tr>
</tbody>
</table>
| Authorization Criteria          | 1. Is the request for continuation of Prevymis (letermovir) therapy?  
|                                 |   a. If yes, clinical review required  
|                                 |   b. If no, continue to #2  
|                                 | 2. Is the request for use to treat an FDA-approved indication? (Provide documentation of diagnosis)  
|                                 |   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 OR within 100 days of transplant if CMV-seropositive with acute graft vs. host disease grade 2-4? (Provide documentation of transplant date)  
|                                 |   a. If yes, continue to #4  
|                                 |   b. If no, clinical review required  
|                                 | 4. Does the member meet one of the following criteria? (Provide documentation of CMV status for recipient or donor if applicable)  
|                                 |   • CMV-seropositive recipient OR  
|                                 |   • CMV seronegative recipient receiving a graft from seropositive donor (CMV D+/R-) who received an HLA-1 mismatched allograft, an umbilical cord blood allograft, or alemtuzumab  
|                                 |   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 documentation of contraindication or rationale for avoidance)  
|                                 |   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 current medication list)  

Last Reviewed: 10/3/18  
Effective Date: 1/1/19
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 unless otherwise specified
   b. If no, clinical review required

Note:
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References:
# Prolia® (denosumab)
## Prior Authorization Guidelines

### Affected Medication(s)
- Prolia subcutaneous solution

### FDA Approved Indication(s)
- Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer.
- Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

### Dosing
- 60 mg subcutaneously once every 6 months

### Initial Authorization Criteria

1. Is the request for continuation of Prolia (denosumab)?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a documented diagnosis of osteoporosis as indicated by one or more of the following? (Provide supporting documentation including DXA report within 2 years)
   - Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -2.5 and/or forearm DXA 33% (one-third) radius
   - T-score less than or equal to -1 or low bone mass AND a history of fragility fracture to the hip or spine
   - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%
   a. If yes, continue to #6
   b. If no, continue to #4

Last Reviewed: 11/7/18
Effective Date: 1/1/19
4. Does the member have non-metastatic prostate cancer and is currently receiving androgen deprivation therapy with confirmed osteopenia? (Provide supporting documentation)
   a. If yes, continue to #13
   b. If no, continue to #5

5. Does the member have breast cancer and is receiving adjuvant aromatase inhibitor with confirmed osteopenia?
   a. If yes, continue to #13
   b. If no, clinical review required

6. Is the member currently on systemic glucocorticoid therapy with a daily dosage equivalent of prednisone 7.5 mg or greater?
   a. If yes, continue to #7
   b. If no, continue to #8

7. Will the member continue with systemic glucocorticoid therapy at a daily dosage equivalent to 7.5 mg or greater of prednisone for at least 6 months?
   a. If yes, continue to #11
   b. If no, continue to #8

8. Is member at high risk for fracture as defined by one or more of the following? (Provide supporting documentation)
   - History of an osteoporotic fracture as an adult
   - Parental history of hip fracture
   - Low BMI
   - Rheumatoid arthritis
   - Alcohol intake of 3 or more drinks per day
   - Current smoking
   - History of oral glucocorticoids ≥ 5 mg/day of prednisone (or equivalent) for > 3 months in lifetime
   a. If yes, continue to #9
   b. If no, clinical review required

9. Does the member have five years of continuous treatment with bisphosphonates? (Provide all prior therapy history)
   a. If yes, continue to #13
   b. If no, continue to #10

10. Does the member have a trial with insufficient response to at least 12 months of bisphosphonate therapy (oral or IV) as defined by a decrease in T-score from baseline or member had a fracture while on bisphosphonate therapy? (Provide past relevant medication list with documentation of response to therapy)
    a. If yes, continue to #13
    b. If no, continue to #11

11. Does the member have a contraindication or intolerance to oral bisphosphonates? (Provide supporting documentation)
12. Does the member with a contraindication or intolerance to IV bisphosphonates? (Provide supporting documentation)
   a. If yes, continue to #13
   b. If no, clinical review required

13. Is the member currently supplementing with at least 1,000 mg of calcium and 400 IU of vitamin D daily that will be continued throughout therapy? (Provide list of current relevant medications)
   a. If yes, continue to #14
   b. If no, clinical review required

14. Does member have any of the following contraindications to treatment with Prolia (denosumab)? (Provide serum calcium level for review)
   - Hypersensitivity to any component of the product
   - Hypocalcemia
   - Pregnancy
   a. If yes, clinical review required
   b. If no, continue to #15

15. Will Prolia (denosumab) be used concurrently with bisphosphonates or a PTH analog?
   a. If yes, clinical review required
   b. If no, continue to #16

16. Is the treatment being prescribed by or in consultation with an endocrinologist, a rheumatologist, or oncologist? (oncologist consultation if the patient has prostate or breast cancer)
   a. If yes, approve for up to 2 years unless otherwise specified
   b. If no, clinical review required

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**Reauthorization Criteria**

1. Does the member continue to meet initial authorization criteria? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member demonstrate positive clinical response to therapy as defined by absence of fractures and/or an increase in bone mineral density from pretreatment baseline? (Provide updated DXA report and other supporting documentation)
   a. If yes, approve for up to 2 years 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)

- Promacta oral tablet

FDA Approved Indication(s)

- For the 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
- For the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy
- For the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy

Dosing

- For ITP:
  o Adult and pediatric patients 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)
  o Pediatric patients 1-5 years old: Initially 25 mg once daily
  o Adjust as outlined in package insert
- Chronic Hepatitis C associated thrombocytopenia:
  o Initially 25 mg once daily
  o Adjust as outlined in package insert, not exceeding a dose of 100 mg daily
- For severe aplastic anemia:
  o Initially 50 mg once daily (if East Asian ancestry or Child-Pugh Class A, B, or C reduce dose to 25mg once daily)
  o Adjust as outlined in package insert, not exceeding a dose of 150mg daily

Initial Authorization Criteria

1. Is the request for continuation of Promacta® (eltrombopag) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. What is the diagnosis that Promacta® (eltrombopag) is being requested for?
   a. Chronic immune (idiopathic) thrombocytopenia (ITP), continue to corresponding criteria
   b. Severe aplastic anemia, continue to corresponding criteria
   c. Other indication, clinical review required
### Chronic immune (idiopathic) thrombocytopenia (ITP)

1. Is the member’s platelet count less than 30 x 10^9/L (30,000/mm)? (Provide platelet count for review)  
   a. If yes, continue to #2  
   b. If no, clinical review required  

2. Has the member had an inadequate response, intolerance, or contraindication to glucocorticoids AND splenectomy or rituximab or immunoglobulins for ITP (Inadequate response defined as platelet count fails to reach greater than or equal to 50 x 10^9/L (50,000/mm))? (Provide supporting documentation for prior treatment history)  
   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?  
   a. If yes, approve for 3 months unless otherwise specified  
   b. If no, clinical review required

### Aplastic anemia

1. Is the member’s platelet count less than 30 x 10^9/L (30,000/mm)? (Provide CBC with differential and platelet count for review)  
   a. If yes, continue to #2  
   b. If no, clinical review required  

2. Has the member had a trial with an inadequate response, an intolerance, or contraindication to 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 unless otherwise specified  
   b. If no, clinical review required

### Reauthorization Criteria

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

2. Were updated chart notes (within previous 6 months) and supporting labs received with documentation meeting one of the following? (Provide supporting documentation including lab results for review)  
   - Confirmed diagnosis of chronic immune (idiopathic) thrombocytopenia ITP with platelet count greater than or equal to 50 x 10^9/L (50,000/mm)  
   - Confirmed diagnosis of severe aplastic anemia with platelet count increases to 20 x 10^9/L above baseline OR stable platelet counts without transfusion for 8 or more weeks or hemoglobin increases by > 1.5 g/dL OR ANC increases 100% or ANC increase > 0.5 x10^9/L
a. If yes, continue to #3
b. If no, clinical review required

3. Is the medication being prescribed by or in consultation with an appropriate specialist for the indicated diagnosis?
   a. If yes, approve for 12 months unless otherwise specified
   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.


**Parathyroid Hormone (PTH) Analog Agents**
**Prior Authorization Guidelines**

**Affected Medication(s)**
- Forteo (teriparatide) subcutaneous solution
- Tymlos (abaloparatide) subcutaneous solution

**FDA Approved Indication(s)**
- Treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy
  - Forteo, Tymlos
- To increase bone mass in men with primary or hypongadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy
  - Forteo
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy
  - Forteo

**Dosing**
- **Forteo**: 20 mcg subcutaneously once daily
- **Tymlos**: 80 mcg subcutaneously once daily
- Parathyroid hormone analogs have a lifetime cumulative treatment duration of 2 years

**Authorization Criteria**

1. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member have a documented diagnosis of osteoporosis as indicated by one or more of the following? (Provide supporting documentation including DXA report within 2 years)
   - Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -2.5 and/or forearm DXA 33% (one-third) radius
   - T-score less than or equal to -1 or low bone mass AND a history of fragility fracture to the hip or spine
   - T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3%
     a. If yes, continue to #3
     b. If no, clinical review required
3. Does the member have a high risk for fracture as defined by one or more of the following? (Provide supporting documentation)
• History of an osteoporotic fracture as an adult
• Parental history of hip fracture
• Low BMI
• Rheumatoid arthritis
• Alcohol intake of 3 or more drinks per day
• Current smoking
• History of oral glucocorticoids ≥ 5 mg/day of prednisone (or equivalent) for > 3 months in lifetime

  a. If yes, continue to #4
  b. If no, clinical review required

4. Does the member have five years of continuous treatment with bisphosphonates? (Provide all prior treatment history)
   a. If yes, continue to #8
   b. If no, continue to #5

5. Does the member have a trial with insufficient response to at least 12 months of bisphosphonate therapy (oral or IV) as defined by a decrease in T-score from baseline or member had a fracture while on bisphosphonate therapy? (Provide past relevant medication list with documentation of response to therapy)
   a. If yes, continue to #8
   b. If no, continue to #6

6. Does the member have a contradiction or intolerance to oral bisphosphonates? (Provide supporting documentation)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Does the member have a contraindication or intolerance to IV bisphosphonates? (Provide supporting documentation)
   a. If yes, continue to #8
   b. If no, clinical review required

8. Does the member have documentation of a trial with insufficient response, an intolerance, or a contraindication to Prolia as defined by a decrease in T-score from baseline or member had a fracture while on Prolia therapy? (Provide past relevant medication list with documentation of response to therapy)
   a. If yes, continue to #9
   b. If no, clinical review required

9. For treatment of postmenopausal women with osteoporosis, is Tymlos being requested?
   a. If yes, continue to #11
   b. If no, continue to #10
   c. If not applicable, continue to #11

10. Is clinical rationale for avoiding Tymlos received? (Provide supporting documentation)
    a. If yes, continue to #11
    b. If no, clinical review required
11. Is the member currently supplementing with at least 1,000 mg of calcium and 400 IU of vitamin D daily that will be continued throughout therapy? (Provide list of current relevant medications)
   a. If yes, continue to #12
   b. If no, clinical review required

12. Is the member’s serum calcium within normal range? (Provide serum calcium level for review)
   a. If yes, continue to #13
   b. If no, clinical review required

13. Does the member have increased risk of osteosarcoma? (i.e. Paget’s disease of bone, unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton)
   a. If yes, clinical review required
   b. If no, continue to #14

14. Will the requested parathyroid hormone analog be used concurrently with Prolia (denosumab), bisphosphonates, or another PTH analog?
   a. If yes, clinical review required
   b. If no, continue to #15

15. Is the treatment being prescribed by or in consultation with an endocrinologist or a rheumatologist?
   a. If yes, approve for 2 years or unless otherwise specified (lifetime therapy limit of 24 months)
   b. If no, clinical review required

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


**Ravicti® (glycerol phenylbutyrate)**
**Prior Authorization Guidelines**

**Affected Medication(s)**
- Ravicti oral solution

**FDA Approved Indication(s)**
- Chronic management of patients 2 months of age and older with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone
  - Must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

**Dosing**
- Refer to package insert for specific dosing recommendations

**Initial Authorization Criteria**

1. Is the request for continuation of Ravicti (glycerol phenylbutyrate) therapy?
   a. If yes, continue to **Reauthorization**
   b. If no, continue to #2

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

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

4. Is the diagnosis confirmed by blood, enzyme, or genetic testing? (Provide lab result for review)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is a baseline plasma ammonia level received? (Provide lab result for review)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Has the member tried a protein restrictive diet alone with an inadequate response? (Provide documentation of trial with response)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Will Ravicti be used in combination with a protein restrictive diet? (Provide documentation of protein restricted diet)
   a. If yes, continue to #8
   b. If no, clinical review required
8. Does the member have a previous trial with inadequate response, intolerance, or contraindication to sodium phenylbutyrate? (Provide documentation of trial, intolerance, or contraindication)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Is the treatment being initiated by a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member show a positive clinical response to therapy as defined by normalized plasma ammonia levels? (Provide documentation of normalized plasma ammonia levels)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Will Ravicti be used in combination with a protein restrictive diet? (Provide documentation of protein restricted diet)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the treatment being prescribed by or in consultation with a provider that specializes in the treatment of inherited metabolic disorders? (Examples include a medical geneticist or an endocrinologist)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:
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References:
## Affected Medication(s)
- Sabril (vigabatrin) oral tablet
- Sabril (vigabatrin) oral packet
- Vigabatrin oral packet

## FDA Approved Indication(s)
- Adjunctive therapy in patients 10 years of age or older with resectable complex partial seizures who had an inadequate response to several alternative treatments
- 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; follow adult dosing in patient weights more than 60 kg
  - Adults: 3000 mg per day
- **Infantile Spasms**: Maximum daily dose of 150 mg/kg

## Initial Authorization Criteria

1. Is the request for continuation of vigabatrin therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

2. Review submitted diagnosis and verify criteria below:
   - 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, tigabine, zonisamide, lacosamide? (Provide history of seizure therapy)
   - a. If yes, continue to #2
   - b. If no, clinical review required

2. Is documentation provided that indicates potential benefits from treatment outweigh the risk of vision loss? (Documentation must confirm member was educated on the risk of vision loss)
   - a. If yes, continue to #3
   - b. If no, clinical review required

3. Was a baseline vision assessment completed?
   - a. If yes, continue #4
   - b. If no, clinical review required
4. Is this a request for the brand name medication?
   a. If yes, continue to #5
   b. If no, continue to #6

5. Is documentation provided that indicates the member is unable to tolerate or has had an inadequate response to the generic medication? (Provide documentation of inadequate response or inability to take generic medication)
   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 12 months, unless otherwise specified
   b. If no, clinical review required

Infantile Spasms

1. Does documentation indicate potential benefits from treatment outweigh the risk of vision loss? (Documentation must confirm that member’s parent or guardian was educated on the risk of vision loss)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is this a request for the brand name medication?
   a. If yes, continue to #3
   b. If no, continue to #4

3. Is documentation provided that indicates the member is unable to tolerate or has had an inadequate response to the generic medication? (Provide documentation of inadequate response or inability to take generic medication)
   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, unless otherwise specified
   b. If no, clinical review required

Reauthorization Criteria

1. Is vigabatrin being prescribed for an FDA-approved indication or major compendia supported use? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Were updated chart notes provided (within 1 year) of clinical response to therapy with documentation of a routine vision assessment performed every 3 months? (Provide documentation of reduction in seizures/infantile spasms)
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, 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)
- Samsca oral tablet

## FDA Approved Indication(s)
- Treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)

## Dosing
- Initially: 15mg once daily
- Titrate as needed to a maximum of 60 mg once daily
- Do administer for more than 30 days to minimize risk of liver injury

## Authorization Criteria
1. **Is the request for use to treat an FDA approved indication?** (Provide documentation of diagnosis)
   - 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, continue to #3
   - b. If no, clinical review required
3. **Does the member have a serum sodium level <125 mEq/L?** (Provide serum sodium level for review)
   - a. If yes, continue to #5
   - b. If no, continue to #4
4. **Does the member have symptomatic hyponatremia despite fluid restriction of <1000mL/day?** (i.e. lethargy, weakness, irritability) (Provide documentation of fluid restriction)
   - a. If yes, continue to #5
   - b. If no, clinical review required
5. **Are drugs known to potentially cause SAIDH being reviewed or discontinued when appropriate?** (i.e. chlorpropamide, SSRIs, TCAs, carbamazepine, vincristine, nictotine, NSAIDs, etc.) (Provide documentation of medication reconciliation)
   - a. If yes, continue to #6
   - b. If no, clinical review required
6. **Does the member have any of the following contraindications to therapy with Samsca (tolvaptan)?**
   - • Autosomal Dominant Polycystic Kidney Disease (ADPKD)
   - • Urgent Need to Raise Serum Sodium Acutely
   - • Inability to Sense or Appropriately Respond to Thirst
   - • Hypovolemic Hyponatremia
- Concomitant Use of Strong CYP 3A Inhibitors
- Anuria
  a. If yes, clinical review required
  b. If no, continue to #7

7. Is the treatment being prescribed by, or in consultation with, an endocrinologist or nephrologist?
  a. If yes, approve for 1 month
  b. If no, clinical review required

Note:
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References:
Affected Medication(s)

- Sandostatin injection solution
- Sandostatin LAR Depot intramuscular powder for suspension
- Octreotide acetate injection solution

FDA Approved Indication(s)

- To reduce blood levels of growth hormone and IGF-I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses
- For the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease
- For the treatment of the profuse watery diarrhea associated with VIP-secreting tumors. Sandostatin studies were not designed to show an effect on the size, rate of growth or development of metastases

Dosing

- Refer to corresponding package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of Sandostatin (octreotide), Sandostatin LAR Depot (octreotide), or octreotide acetate therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved or major compendia supported indication? (Provide documentation of diagnosis)
   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. What diagnosis is the medication being requested for? (Provide supporting documentation)
   a. Carcinoid tumors/Neuroendocrine tumors (e.g. GI tract, lung, thymus, pancreas, adrenal), continue to corresponding criteria
   b. Diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) [pancreatic, neuroendocrine (islet cell) tumor, insulinoma, glucagonoma, somatostatinoma, and gastrinoma], continue to corresponding criteria
   c. Acromegaly, continue to corresponding criteria
   d. Oncology indication, continue to corresponding criteria
   e. Other non-oncology indication(s), continue to corresponding criteria
Carcinoid tumors/Neuroendocrine tumors (e.g. GI tract, lung, thymus, pancreas, adrenal)

1. Does the member meet one or more of the following conditions? (Provide supporting documentation)
   - Severe diarrhea/flushing episodes (carcinoid syndrome)
   - Requested use is to treat symptoms related to hormone hypersecretion in pancreatic tumors
   - Requested use is for primary treatment of unresected primary gastrinoma
   - Requested use is for management of locoregional advanced or metastatic disease of the bronchopulmonary, thymic, gastrointestinal tract
   - Requested use is for tumor control of unresectable and/or metastatic tumors of the pancreas
     a. If yes, approve for 6 months unless otherwise specified
     b. If no, clinical review required

Diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) [pancreatic, neuroendocrine (islet cell) tumor, insulinoma, glucagonoma, somatostatinoma, and gastrinoma]

1. Does the member have profuse watery diarrhea? (Provide supporting documentation)
   a. If yes, approve for 6 months
   b. If no, clinical review required

Acromegaly

1. Are baseline growth hormone (GH) and IGF-1 blood levels received? (Provide GH and IGF-1 serum levels for review)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Did the member have an inadequate response to surgery and/or radiotherapy or is the member not a candidate for surgery and/or radiotherapy? (Provide documentation of inadequate response or rationale why member is not a candidate)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Oncology Indication

1. Is the medication being requested for an indication supported by National Comprehensive Cancer Network (NCCN) 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 #2
   b. If no, clinical review required
2. 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 #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 4 months unless otherwise specified
   b. If no, clinical review required
Other Non-Oncology Indication

1. 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 documentation of inadequate response, contraindication, and/or intolerance)
   a. If yes, continue to #2
   b. If no, clinical review required

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

Reauthorization Criteria

1. Does the member continue to meet the initial authorization criteria? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is there documentation of any of the following side effects from the medication? (Examples of unacceptable toxicity include the following: biliary tract abnormalities, hypothyroidism, goiter, sinus bradycardia, cardiac arrhythmias, cardiac conduction abnormalities, pancreatitis, etc.) (Provide supporting documentation of absence of unacceptable toxicities)
   a. If yes, clinical review required
   b. If no, continue to #3

3. Does the member have a positive clinical response to therapy defined by one of the following? (Provide supporting documentation)
   - Improvement in symptoms including reduction in symptomatic episodes (such as diarrhea, rapid gastric dumping, flushing, bleeding, etc)
   - Stabilization of glucose levels
   - Decrease or stabilization in tumor size
   - For acromegaly only: Reduction of growth hormone (GH) and/or IGF-I blood levels from baseline
   - For neuroendocrine tumors of the pancreas only: Member has had disease progression and therapy will be continued in member with functional tumors in combination with systemic therapy
   a. If yes, continue to #4
   c. If no, clinical review required

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

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References:


4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Octreotide. 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."
**Affected Medication(s)**

- Addyi (flibanserin) oral tablet
- Caverject (alprostadil) powder for reconstitution and intracavernos injection
- Cialis (tadalafil) oral tablet
- Edex (alprostadil) injection
- Levitra (vardenafil) oral tablet
- Muse (alprostadil) urethral suppository
- Sildenafil oral tablet
- Staxyn (vardenafil) orally disintegrating tablet
- Stendra (avanadil) oral tablet
- Tadalafil oral tablet
- Vardenafil oral tablet and orally disintegrating tablet
- Viagra (sildenafil) oral tablet

**FDA Approved Indication(s)**

- For the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance
  - Addyi
  - For the treatment of erectile dysfunction
  - Caverject, Cialis Levitra, sildenafil, Muse, Staxyn, Stendra, tadalafil, vardenafil, Viagra
- Adjunct to other diagnostic tests in the diagnosis of erectile dysfunction (ED)
- Caverject:
- For the treatment of signs and symptoms of benign prostatic hyperplasia (BPH)
  - Cialis, tadalafil
- Treatment of erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia (ED/BPH)
  - Cialis, tadalafil

**Dosing**

- Refer to corresponding package insert for specific dosing recommendations

**Initial Authorization Criteria**

1. Is the request for continuation of therapy with the same agent used for the same indication?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Which diagnosis is the medication being requested for?
   a. Erectile disorder, continue to corresponding criteria
   b. Female sexual interest/arousal disorder, continue to corresponding criteria
   c. As an adjunct to other diagnostic tests for diagnosis of erectile dysfunction, approve for one dose
   d. Benign prostatic hyperplasia, continue to corresponding criteria

### Erectile Disorder

1. Does the member experience one or more of the following symptoms on at least 75% of sexual activity for a duration of 6 months or greater? (Provide supporting documentation)
   - Marked difficulty in obtaining an erection during sexual activity
   - Marked difficulty in maintaining an erection until the completion of sexual activity
   - Marked decrease in erectile rigidity
     
     a. If yes, continue to #2
     b. If no, clinical review required

2. Do the above symptoms cause the member clinically significant distress? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Have other causes of sexual dysfunction been ruled out such as nonsexual mental disorder, severe relationship distress, other significant stressor, substance/medication side effect, and/or other medical condition (Provide supporting documentation)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

### Female Sexual Interest/ Arousal Disorder

1. Does the member demonstrate a lack of, or significantly reduced, sexual interest/arousal as manifested by at least 3 of the following? (Provide supporting documentation)
   - Absent/reduced interest in sexual activity
   - Absent/reduced sexual/erotic thoughts or fantasies
   - No/reduced initiation of sexual activity, and typically unreceptive to a partner’s attempts to initiate
   - Absent/reduced sexual excitement/pleasure during sexual activity in almost all or all (approximately 75%–100%) sexual encounters (in identified situational contexts or, if generalized, in all contexts)
   - Absent/reduced sexual interest/arousal in response to any internal or external sexual/erotic cues (e.g., written, verbal, visual)
   - Absent/reduced genital or non-genital sensations during sexual activity in almost all or all (approximately 75%–100%) sexual encounters (in identified situational contexts or, if generalized, in all contexts)
     
     a. If yes, continue to #2
     b. If no, clinical review required

2. Have the above symptoms persisted for a duration of 6 months or longer? (Provide supporting documentation of symptom duration)
a. If yes, continue to #3
   b. If no, clinical review required

3. Do the member’s sexual symptoms cause the member clinically significant distress? (Provide supporting documentation)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Have other causes of sexual dysfunction been ruled out such as nonsexual mental disorder, severe relationship distress, other significant stressor, substance/medication side effect, and/or other medical condition? (Provide supporting documentation)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Benign Prostatic Hyperplasia

1. Does the member have documentation of a trial with inadequate response or intolerance to at least one alpha-adrenergic blocker (tamsulosin, doxazosin, terazosin, alfuzosin) AND one 5-alpha reductase inhibitor (finasteride or dutasteride)? (Provide supporting documentation of trials with inadequate response, intolerances, or contraindications)
   a. If yes, approve for 12 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member demonstrate a positive clinical response from therapy as defined by one of the below?
   - For erectile disorder: Improvement in obtaining and maintaining an erection
   - For female sexual interest/arousal disorder: Improvement in sexual interest and/or sexual arousal
   - For benign prostatic hyperplasia: Improvement in urinary frequency, urinary urgency, nocturia, and/or incomplete emptying
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

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References:


5. Staxyn (vardenafil) [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline LLC. August 2017


### Affected Medication(s)
- Signifor subcutaneous solution

### FDA Approved Indication(s)
- For treatment of adult patients with Cushing’s disease for whom pituitary surgery is not an option or has not been curative

### Dosing
- 0.3 to 0.9 mg by subcutaneous injection twice a day

### Initial Authorization Criteria

1. Is the request for continuation of Signifor (pasireotide) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Did the member either have pituitary surgery that was not curative or is the member not a candidate for surgery? (Provide supporting documentation confirming persistent hypercortisolism)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the requested medication being prescribed or in consultation with an endocrinologist?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member demonstrate a positive clinical response to therapy as defined by a reduction in 24-hour urinary free cortisol levels or improvement in signs and symptoms of Cushing’s disease? (Provide supporting documentation)
   c. If yes, continue to #3
   d. If no, clinical review required

3. Is the requested medication being prescribed 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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References:
**Sirturo® (bedaquiline fumarate)**
**Prior Authorization Guidelines**

**Affected Medication(s)**

- Sirturo oral tablet

**FDA Approved Indication(s)**

- As part of combination therapy in the treatment of adults (18 years and older) with pulmonary multi-drug resistant tuberculosis (MDR-TB)
- Reserve for use when an effective treatment regimen cannot otherwise be provided

**Dosing**

- 400 mg orally once daily for the first two weeks, followed by 200 mg orally three times per week (with at least 48 hours between doses) for 22 weeks (total duration of 24 weeks)

**Authorization Criteria**

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

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

3. Is the member’s isolate of *M. tuberculosis* resistant to both isoniazid AND rifampin or does the member have a contraindication or intolerance to therapy with isoniazid or rifampin? (Provide documentation of resistant isolate, contraindication, or intolerance)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is Sirturo being used with at least 3 other susceptible agents OR with at least 4 other likely susceptible agents for the treatment of MDR-TB? (Provide documentation of susceptible isolate and planned treatment regimen)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the treatment being prescribed by, or in consultation with, an infectious disease specialist or pulmonologist?
   a. If yes, approve for 24 weeks otherwise specified
   b. If no, clinical review required

**Note:**

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Last Reviewed: 11/21/18
Effective Date: 1/1/19
References:


# Somavert® (pegvisomant) 
Prior Authorization Guidelines

<table>
<thead>
<tr>
<th>Affected Medication(s)</th>
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</thead>
<tbody>
<tr>
<td>Somavert subcutaneous powder for solution</td>
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<table>
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<tr>
<th>FDA Approved Indication(s)</th>
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<tbody>
<tr>
<td>Treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate</td>
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</table>

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<tr>
<th>Dosing</th>
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<tbody>
<tr>
<td>Loading Dose: 40 mg subcutaneously</td>
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<tr>
<td>Maintenance Dose: 10 mg subcutaneously once daily, starting the day after loading dose administration</td>
</tr>
</tbody>
</table>

## Initial Authorization Criteria

1. Is the request for continuation of Somavert (pegvisomant) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have an elevated insulin like growth factor-1 (IGF-1) level for age and gender? (Provide baseline IGF-1 level for review)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have a trial with inadequate response to, or documentation supporting they are not a candidate for either surgery or radiation therapy? (Provide documentation of inadequate response or rationale for avoiding therapy)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Is the treatment being prescribed by, or in consultation with, an endocrinologist?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Has the member had a positive clinical response to therapy as defined as either a decrease in or normalization in insulin like growth factor for age and gender (IGF-1)? (Provide documentation of IGF-1 value for review)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the treatment 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

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:
**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 with fat-containing food

**Initial Authorization Criteria**

1. Is the request for continuation of Symdeko® (tezacaftor/ivacaftor) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

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

3. Does the member have a documentation of homozygous F508del mutation by a FDA-cleared CF mutation test? (Provide report for review)
   - a. If yes, continue to #5
   - b. If no, continue to #4

4. Does the member 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 report for review)
   - a. If yes, continue to #5
   - b. If no, clinical review required

5. Has documentation of pulmonary function (baseline FEV1) and liver function (ALT and AST) been provided and are the liver enzymes within normal range? (Provide documentation of pulmonary and liver tests for review)
   - a. If yes, continue to #6
   - b. If no, clinical review required

6. Is Symdeko® (tezacaftor/ivacaftor) being prescribed by, or in consult with, a pulmonologist or a specialist experienced in treating cystic fibrosis?
   - a. If yes, approve for 6 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 documentation of diagnosis)**
   - 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? (Provide documentation of improvement of FEV1 from baseline)**
   - 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 documentation of AST and ALT for review)**
   - 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 specialist experienced in treating cystic fibrosis?**
   - 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:

Symlinpen® (pramlintide acetate)
Prior Authorization Guidelines

**Affected Medication(s)**
- Symlinpen subcutaneous solution

**FDA Approved Indication(s)**
- An adjunctive treatment in patients with type 1 or type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy

**Dosing**
- **Type 2 diabetes:**
  - Initiate 60 mcg before each meal
  - May titrate to 120 mcg before each meal
- **Type 1 diabetes:**
  - Initiate 15 mcg before each meal
  - May titrate up to 60 mcg before each meal

**Initial Authorization Criteria**

1. Is the request for continuation of Symlinpen (pramlintide acetate) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is the member currently taking mealtime insulin and plans to remain on mealtime insulin throughout therapy with Symlinpen (pramlintide acetate)? (Provide documentation of relevant medication history and treatment plan)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Has the member failed to achieve glucose control despite insulin adherence and titration? (Provide documentation of insulin titration and response to dosing titration)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have an HbA1c that is greater than 7% and less than or equal to 9%? (Provide HbA1C result for review)
   a. If yes, continue to #6
   b. If no, clinical review required
6. Does the member have a history of recurrent hypoglycemia requiring assistance in the past 6 months or a history of hypoglycemia unawareness? (Provide documentation of relevant past medical history including any hypoglycemia episodes requiring assistance)
   a. If yes, clinical review required
   b. If no, approve for 6 months unless otherwise specified

### Reauthorization Criteria

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

2. Is the member currently taking insulin and plans to remain on insulin throughout therapy with Symlinpen (pramlintide acetate)? (Provide documentation of treatment plan)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member show a positive clinical response to therapy defined as an HbA1c of less than or equal to 9%? (Provide documentation of HbA1c result for review)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

**Note:**

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**References:**

Synagis® (palivizumab)
Prior Authorization Guidelines

Affected Medication(s)
- Synagis intramuscular solution

FDA Approved Indication(s)
- Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients:
  o 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
  o 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
  o 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
  o 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

Authorization Criteria
1. Is the request for a compendia supported indication? (Provide documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the member's weight provided for review? (Provide documentation of member weight)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a history of hospitalization for RSV infection during the current RSV season?
   a. If yes, clinical review required
   b. If no, continue to #4
4. 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 documentation of gestation age for review)
a. If yes, continue to #2  
b. If no, clinical review required

2. Is the member <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 treatment plan for review)
   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 gestational age of <32 weeks? (Provide documentation of gestational age for review)
   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 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 documentation
   of cardiopulmonary bypass)
   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? (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 documentation of weigh for length percentile for review)
   a. If yes, approve for up to 5 doses during RSV season
   b. If no, clinical review required

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References:
# Testopel® (testosterone)
## Prior Authorization Guidelines

### Affected Medication(s)
- Testopel subcutaneous implant

### FDA Approved Indication(s)
- Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome, or orchiectomy
- Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation

### Dosing
- 150-450 mg subcutaneously implant every 3 to 6 months

### Initial Authorization Criteria

1. Is the request for continuation of therapy of Testopel (testosterone) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

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

3. Does the member have a trial with insufficient response or intolerance to BOTH generic intramuscular testosterone AND topical testosterone? (Provide documentation of trials with insufficient response, or intolerances)
   - a. If yes, continue to #4
   - b. If no, clinical review required

4. What indication is the topical testosterone medication being requested for?
   - a. Hypogonadism, continue to corresponding criteria
   - b. Gender Dysphoria, continue to corresponding criteria

### Hypogonadism

1. Is the member currently taking testosterone replacement therapy? (Provide documentation of testosterone replacement therapy history)
   - a. If yes, continue to #2
   - b. If no, continue to #3

2. Does the member have a testosterone level that was taken in the morning that is either within normal range or below normal (below normal range: total testosterone < 300 ng/dL or free testosterone <5 ng/dL)? (Provide documentation of testosterone level)
   - a. If yes, continue to #4
b. If no, clinical review required

3. Does the member have documentation of TWO baseline testosterone levels, taken in the mornings of different days, that are below normal range (total testosterone< 300 ng/dL or free testosterone <5ng/dL)? (Provide documentation of testosterone levels)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have at least TWO signs/symptoms of hypogonadism (For members currently on testosterone therapy, have they experienced at least TWO signs/symptoms of hypogonadism prior to initiation of therapy)? (examples include sleep disturbances, gynecomastia, decreased lean body mass, visceral obesity, hot flashes, changes in mood, cognitive impairment, insulin resistance, anemia, and low bone mineral density) (Provide supporting documentation of signs/symptoms)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Gender Dysphoria

1. Does the member have a diagnosis of gender identity disorder 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, continue to #3
   b. If no, clinical review required

3. 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, approve for 6 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 documentation of diagnosis)
   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 total serum testosterone level that is within normal range? (Provide documentation of testosterone levels)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required
Note:
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References:
## Therapeutic Immunomodulators
### Prior Authorization Guidelines

**Affected Medication(s)**
- Actemra (tocilizumab) subcutaneous solution
- Cimzia (certolizumab pegol) subcutaneous solution
- Cosentyx (secukinumab) subcutaneous solution
- Enbrel (etanercept) subcutaneous solution
- Humira (adalimumab) subcutaneous solution
- Ilumya (tildrakizumab-asmn) subcutaneous solution
- Kevzara (sarilumab) subcutaneous solution
- Kineret (anakinra) subcutaneous solution
- Olumiant (baricitinib) oral tablet
- Orencia (abatacept) subcutaneous solution
- Otezla (apremilast) oral tablet
- Siliq (brodalumab) subcutaneous solution
- Simponi (golimumab) subcutaneous solution
- Stelara (ustekinumab) subcutaneous solution
- Taltz (ixequizumab) subcutaneous solution
- Xeljanz (tofacitinib citrate) oral tablet
- Xeljanz XR (tofacitinib citrate ER) oral tablet

**FDA Approved Indication(s)**
- Drug Compendia supported indications may be covered

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**Dosing**
- Refer to corresponding package insert for information
# Initial Authorization Criteria

1. **Is the request for continuation of therapeutic immunomodulatory therapy?**
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

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

3. **Will the requested medication be used concurrently with any other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Orenzia, Taltz, Cosentyx, Otezla, 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, continue to corresponding criteria
   - b. Juvenile idiopathic arthritis, continue to corresponding criteria
   - c. Ankylosing spondylitis, continue to corresponding criteria
   - d. Psoriatic arthritis, continue to corresponding criteria
   - e. Crohn’s disease, continue to corresponding criteria
   - f. Ulcerative colitis, continue to corresponding criteria
   - g. Plaque psoriasis, continue to corresponding criteria
   - h. Hidradenitis suppurativa, continue to corresponding criteria
   - i. Uveitis, continue to corresponding criteria
   - j. Other indication not listed, continue to corresponding criteria

## Rheumatoid Arthritis (RA)

1. **Is the diagnosis of rheumatoid arthritis (RA) confirmed by ACR/EULAR classification criteria AND has the diagnosis 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 RA confirmed by one of the tests below and despite the current RA management regimen? (Provide test result for review and provide current RA management regimen)**
   - 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 documentation of inadequate response to methotrexate)
   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? (Provide documentation of contraindication and/or intolerance)
   a. If yes, continue to #5
   b. If no, clinical review required

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), or hydroxychloroquine (Plaquenil)? (Provide documentation of 12 week trial and response to therapy)
   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 documentation of contraindications and/or intolerances)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Is the request for Humira (adalimumab) or Enbrel (etanercept)?
   a. If yes, continue to #12
   b. If no, continue to #8

8. Is the request for either Kevzara (sarilumab), Xeljanz (tofacitinib), or Xeljanz XR (tofacitinib)?
   a. If yes, continue to #9
   b. If no, continue to #10

9. Does the member have a documented inadequate response, contraindication, or intolerance to BOTH of the following agents: Humira (adalimumab) and Enbrel (etanercept)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
   a. If yes, continue to #12
   b. If no, clinical review required

10. Does the member have a documented inadequate response, contraindication, or intolerance to BOTH of the following agents: Humira (adalimumab) and Enbrel (etanercept)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
    a. If yes, continue to #11
    b. If no, clinical review required

11. Does the member have a documented inadequate response, contraindication, or intolerance to BOTH of the following agents: Kevzara (sarilumab) AND either Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
    a. If yes, continue to #12
    b. If no, clinical review required
12. Is the medication being prescribed by or in consultation with a rheumatologist?
   a. If yes, approve 6 months unless otherwise specified
   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 joints with limitation in motion? (Provide documentation of affected joints and current 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 documentation of trial with inadequate response)
   a. If yes, continue to #5
   b. If no, continue to #3

3. Does the member have a contraindication or history of intolerance to methotrexate? (Provide documentation of contraindication and/or intolerance)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Did the member have a contraindication or history of intolerance to leflunomide (Arava)? (Provide documentation of contraindication and/or intolerance)
   a. If yes, continue to #5
   b. If no, deny. Clinical criteria not met

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

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

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

### Ankylosing Spondylitis (AS)

1. Does the member currently have active AS despite a current treatment regimen as defined by the below? (Provide supporting documentation)
   - Bath ankylosing spondylitis disease activity index (BASDAI) greater or equal to 4
• Ankylosing Spondylitis Disease Activity Score (ASDAS) greater or equal to 2.1 AND
• Elevated CRP, positive MRI, or Radiographic sacroiliitis
  
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 documentation of NSAIDs tried, examples: ibuprofen, naproxen, diclofenac, meloxicam, etc)
  
a. If yes, continue to #4
b. If no, continue to #3

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

4. Does the member have isolated sacroilitis, 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 documentation of trial with inadequate response)
  
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 documentation of contraindication)
  
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 documentation of trial with inadequate response)
  
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 documentation of contraindication and/or intolerance)
  
a. If yes, continue to #9
b. If no, clinical review required

9. Is the request for Humira (adalimumab) or Enbrel (etanercept)?
  
a. If yes, continue to #14
b. If no, continue to #10

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

11. Does the member have a documented inadequate response, intolerance, or contraindication to BOTH of the following agents: Humira (adalimumab) AND Enbrel (etanercept)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
   a. If yes, continue to #14
   b. If no, clinical review required

12. Does the member have a documented inadequate response, intolerance, or contraindication to BOTH of the following agents: Humira (adalimumab) AND Enbrel (etanercept)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
   a. If yes, continue to #13
   b. If no, clinical review required

13. Does the member have a documented inadequate response, intolerance, or contraindication to Cosentyx (secukinumab)? (Provide documentation of inadequate response, contraindication, and/or intolerance)
   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?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Psoriatic Arthritis (PsA)

1. Does the member currently have active PsA defined as greater or equal to 3 swollen joints AND greater or equal to 3 tender or painful joints despite the current treatment regimen? (Provide documentation of affected joints and current treatment regimen)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have predominantly axial disease or severe enthesitis?
   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 documentation of NSAIDs tried, examples: ibuprofen, naproxen, diclofenac, meloxicam, etc)
   a. If yes, continue to #9
   b. If no, continue to #4

4. Does the member have a contraindication to oral NSAIDs? (Provide documentation of contraindication)
   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 documentation of trial with inadequate response)
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? (Provide documentation of contraindication and/or intolerance)
   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 documentation of 12 week trial with inadequate response)
   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 documentation of contraindications and/or intolerances)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Is the request for Humira (adalimumab) or Enbrel (etanercept)?
   a. If yes, continue to #14
   b. If no, continue to #10

10. Is the request for either Cosentyx (secukinumab), Xeljanz (tofacitinib), or Xeljanz XR (tofacitinib)?
    a. If yes, continue to #11
    b. If no, continue to #12

11. Does the member have a documented inadequate response, contraindication, or intolerance to BOTH of the following agents: Humira (adalimumab) AND Enbrel (etanercept)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
    a. If yes, continue to #14
    b. If no, clinical review required

12. Does the member have a documented inadequate response, contraindication, or intolerance to BOTH of the following agents: Humira (adalimumab) AND Enbrel (etanercept)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
    a. If yes, continue to #13
    b. If no, clinical review required

13. Does the member have a documented inadequate response, contraindication, or intolerance to BOTH of the following agents: Cosentyx (secukinumab) AND either Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
    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 unless otherwise specified
b. If no, clinical review required

**Crohn’s Disease (CD)**

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

2. Did the member have an inadequate response to TWO of the following oral agents for a minimum trial of 12 weeks each: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate, mesalamine? (Provide documentation of 12 week trials with inadequate responses)
   a. If yes, continue to #4
   b. If no, continue to #3

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

4. Is the medication being requested for Humira (adalimumab)?
   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 unless otherwise specified
   b. If no, clinical review required

**Ulcerative Colitis (UC)**

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

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

3. Does the member have a contraindication or history of intolerance to at least TWO of the following oral agents: 6-mercaptopurine, azathioprine, corticosteroids, methotrexate, mesalamine, sulfasalazine? (Provide documentation of contraindications and/or intolerances)
   a. If yes, continue to #4
   b. If no, clinical review required
<table>
<thead>
<tr>
<th>No.</th>
<th>Question</th>
<th>Option 1</th>
<th>Option 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>Is the medication being requested for Humira (adalimumab)?</td>
<td>a. If yes, continue to #7</td>
<td>b. If no, continue to #5</td>
</tr>
<tr>
<td>5.</td>
<td>Is the request for Xeljanz (tofacitinib)?</td>
<td>a. If yes, continue to #6</td>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td>6.</td>
<td>Does the member have a documented inadequate response, intolerance, or contraindication to Humira (adalimumab)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)</td>
<td>a. If yes, continue to #7</td>
<td>b. If no, clinical review required</td>
</tr>
<tr>
<td>7.</td>
<td>Is the medication being prescribed by, or in consultation with, a gastroenterologist?</td>
<td>a. If yes, approve for 6 months unless otherwise specified</td>
<td>b. If no, clinical review required</td>
</tr>
</tbody>
</table>

**Plaque Psoriasis (Ps)**

1. Does the member currently have moderate to severe chronic Ps 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 documentation of functional impairment and body area involvement)
   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 systemic therapies: methotrexate, cyclosporine, phototherapy? (Provide documentation of 12 week trials with inadequate responses)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the medication being requested for Humira (adalimumab) or Enbrel (etanercept)?
   a. If yes, continue to #8
   b. If no, continue to #4

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

5. Does the member have documentation of an inadequate response, intolerance, or contraindication to BOTH of the following agents: Humira (adalimumab) AND Enbrel (etanercept)? (Provide documentation of inadequate response, contraindication, and/or intolerance)
   a. If yes, continue to #8
   b. If no, clinical review required
6. Does the member have documentation of an inadequate response, intolerance, or contraindication to BOTH of the following agents: Humira (adalimumab) AND Enbrel (etanercept)? (Provide documentation of inadequate response, contraindication, and/or intolerance)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Does the member have documentation of an inadequate response, intolerance, or contraindication to Cosentyx (secukinumab)? (Provide documentation of inadequate response, contraindication, and/or intolerance)
   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, continue to #8
   b. If no, clinical review required

Hidradenitis Suppurativa
1. Does the member have Hurley stage III Hidradenitis Suppurativa? (Provide documentation of Hurley stage)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Did the member have a previous inadequate response to oral antibiotics? (Provide documentation of oral antibiotic regimen trialed and inadequate response)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the request for Humira (adalimumab)?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, continue to #4

4. Does the member have documentation of inadequate response, intolerance, or contraindication to Humira? (Provide documentation of inadequate response, contraindication, and/or intolerance)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Uveitis
1. Does the member have a diagnosis of non-infectious intermediate, posterior uveitis or panuveitis?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have an inadequate response, intolerance, or contraindication to at least TWO of the following: cyclosporine, systemic glucocorticoids, and/or an antimetabolite (i.e. mycophenolate, methotrexate, or azathioprine)? (Provide documentation of inadequate responses, contraindications, and/or intolerances)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is the request for Humira (adalimumab)?
a. If yes, approve for 6 months unless otherwise specified  
b. If no, continue to #4

4. Does the member have documentation of an inadequate response, intolerance, or contraindication to Humira? (Provide documentation of inadequate response, contraindication, and/or intolerance)  
   a. If yes, approve for 6 months unless otherwise specified  
   b. If no, clinical review required

**Other Indications**

1. Is the request for a FDA approved indication?  
   a. If yes, continue to #4  
   b. If no, continue to #2

2. Is the requested use supported by major compendia not otherwise excluded by plan design?  
   a. If yes, continue to #3  
   b. If no, clinical review required

3. 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 documentation of inadequate responses, contraindications, and/or intolerances)  
   a. If yes, continue to #4  
   b. If no, clinical review required

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

**Reauthorization Criteria**

1. Is the documented indication FDA-approved or supported by major compendia? (Provide documentation of diagnosis)  
   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. Will the requested medication be used with other biologic therapy? (Examples: Enbrel, Actemra, Cimzia, Simponi, Orenica, Taltz, Cosentyx, Otezla, etc)  
   a. If yes, clinical review required  
   b. If no, continue to #4

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

Note:
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References:


## Affected Medication(s)
- Androderm (testosterone) transdermal patch
- Androgel (testosterone) topical gel
- Axiron (testosterone) topical solution
- Fortesta (testosterone) topical gel
- Striant (testosterone) buccal patch
- Testim (testosterone) topical gel
- Testosterone pump, gel, and solution
- Vogelxo (testosterone) topical gel

## FDA Approved Indication(s)
- Primary hypogonadism (congenital or acquired): Testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals
- Hypogonadotropic hypogonadism (congenital or acquired): Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation

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

## Initial Authorization Criteria
1. Is the request for continuation of therapy with the same topical testosterone therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a trial with insufficient response, or intolerance to generic intramuscular testosterone? (Provide documentation of trial with insufficient response or intolerance)
   a. If yes, continue to #4
   b. If no, clinical review required
4. What indication is the topical testosterone medication being requested for?
   a. Hypogonadism, continue to corresponding criteria
   b. Gender dysphoria, continue to corresponding criteria
**Hypogonadism**

1. Is the member currently taking testosterone replacement therapy? (Provide documentation of testosterone replacement therapy history)
   a. If yes, continue to #2
   b. If no, continue to #3

2. Does the member have a testosterone level that was taken in the morning that is either within normal range or below normal (below normal range: total testosterone < 300 ng/dL or free testosterone <5 ng/dL)? (Provide documentation of testosterone level)
   a. If yes, continue to #4
   b. If no, clinical review required

3. Does the member have documentation of TWO baseline testosterone levels, taken in the mornings of different days, that are below normal range (total testosterone< 300 ng/dL or free testosterone <5ng/dL)? (Provide documentation of testosterone levels)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Does the member have at least TWO signs/symptoms of hypogonadism (If member is currently on testosterone therapy, did they experience at least TWO signs/symptoms before initiation of therapy)? (Examples include sleep disturbances, gynecomastia, decreased lean body mass, visceral obesity, hot flashes, changes in mood, cognitive impairment, insulin resistance, anemia, and low bone mineral density) (Provide supporting documentation of signs/symptoms)
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

**Gender Dysphoria**

1. Does the member have a diagnosis of gender identity disorder 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, continue to #3
   b. If no, clinical review required

3. 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, approve for 6 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 documentation of diagnosis)
   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 total serum testosterone level that is within normal range? (Provide documentation of testosterone levels)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:
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References:
Vecamyl® (mecamylamine hydrochloride)
Prior Authorization Guidelines

Affected Medication(s)

- Vecamyl oral tablet

FDA Approved Indication(s)

- Management of moderately severe to severe essential hypertension and in uncomplicated cases of malignant hypertension

Dosing

- Refer to package insert for specific dosing recommendations

Initial Authorization Criteria

1. Is the request for continuation of Vecamyl (mecamylamine hydrochloride) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2
2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a trial with insufficient response, intolerance, or contraindication to at least 3 formulary anti-hypertensives from 3 different therapeutic classes at maximum tolerated doses (i.e. ACE-inhibitors, ARBs, thiazides, calcium channel blockers, beta-blockers, alpha-blockers)? (Provide relevant past treatment history)
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Does the member demonstrate a positive response to therapy as defined by a decrease in blood pressure from baseline? (Provide supporting documentation)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Note:

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Last Reviewed: 11/7/18
Effective Date: 1/1/19
References:


## Veltassa® (patiromer)
### Prior Authorization Guidelines

### Affected Medication(s)
- Veltassa powder for suspension

### FDA Approved Indication(s)
- Treatment of hyperkalemia (should not be used as an emergency treatment for life-threatening hyperkalemia)

### Dosing
- Initially 8.4 g once daily
- Titrate as needed to maximum of 25.2 g once daily to reach desired serum potassium concentration

### Initial Authorization Criteria

1. Is the request for continuation of Veltassa (patiromer) therapy?
   - a. If yes, continue to Reauthorization
   - b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   - 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. Is the baseline potassium level received? (Provide documentation of lab)
   - a. If yes, continue to #5
   - b. If no, clinical review required

5. Have potentially hyperkalemia contributing medications such as NSAIDs, ACEI, ARB, or aldosterone antagonists been reduced or discontinued if clinically appropriate? (Provide documentation of dose reduction/discontinuation or rationale why patient is not a candidate to do so)
   - a. If yes, continue to #6
   - b. If no, clinical review required

6. Does the member follow a low potassium diet? (Provide documentation of diet with 3 or less grams of potassium per day)
   - a. If yes, continue to #7
   - b. If no, clinical review required

7. Does the member have a trial with inadequate response, intolerance, or contraindication to treatment with sodium polystyrene sulfonate? (Provide documentation of trial, intolerance, or contraindication)
   - a. If yes, approve for 6 months unless otherwise specified
Reauthorization Criteria

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

2. Does the member have a positive response to therapy as defined as a decrease in serum potassium? (Provide documentation of decrease in serum potassium compared to pre-treatment)
   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:
VMAT2 Inhibitors
Prior Authorization Guidelines

Affected Medication(s)
- Austedo (deutetrabenazine) oral tablet
- Xenazine (tetrabenazine) oral tablet
- Ingrezza (valbenazine) oral capsule

FDA Approved Indication(s)
- **Austedo:**
  - For the treatment of chorea associated with Huntington's disease
  - For the treatment of tardive dyskinesia in adults
- **Xenazine:**
  - For the treatment of chorea associated with Huntington's disease
- **Ingrezza:**
  - For the treatment of tardive dyskinesia in adults

Dosing
- Refer to package insert for recommended dosing

Initial Authorization Criteria

1. Is the request for continuation of vesicular monoamine transporter 2 (VMAT2) inhibitor therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. What is the diagnosis the medication is being requested for?
   a. Chorea associated with Huntington's disease, continue to corresponding criteria
   b. Tardive dyskinesia, continue to corresponding criteria

Chorea associated with Huntington’s Disease

1. Does the member have a diagnosis of Huntington's disease as defined by ALL of the following? (Provide supporting documentation)
   - DNA testing showing CAG expansion of ≥ 36
   - Family history (if known)
   - Classic presentation (choreiform movements, psychiatric problems, and dementia)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the members’ chorea causing functional impairment in activities of daily life? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is Austedo (deutetrabenazine) being requested?
   a. If yes, continue to #4
   b. If no, continue to #5

4. Does the member have a trial with insufficient response, intolerance, or contraindication to tetrabenazine? (Provide documentation of trial with inadequate response, intolerance, or contraindication)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have any of the following contraindications to the requested treatment?
   • Suicidal, or have untreated or inadequately treated depression
   • Hepatic impairment
   • Taking concurrently with monoamine oxidase inhibitors (MAOIs) or reserpine
   • Taking concurrently with other VMAT2 inhibitors
   a. If yes, clinical review required
   b. If no, continue to #6

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

Tardive dyskinesia

1. Has the patient been taking a dopamine receptor blocking agent for at least 3 months that contributed to the diagnosis? (Provide current/past medication history)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a diagnosis of moderate to severe tardive dyskinesia as defined by an Abnormal Involuntary Movement Scale (AIMS) score of ≥8 or an Extrapyramidal Symptom Rating Scale (ESRS) score of ≥20? (Provide supporting documentation and movement scale score)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is Austedo (deutetrabenazine) or Ingrezza (valbenazine) being requested?
   a. If yes, continue to #4
   b. If no, continue to #5

4. Does the member have a trial with insufficient response, intolerance, or contraindication to tetrabenazine? (Provide documentation of trial with inadequate response, intolerance, or contraindication)
   a. If yes, continue to #5
b. If no, clinical review required

5. Does the member have any of the following contraindications to the requested treatment?
   • Suicidal, or have untreated or inadequately treated depression
   • Hepatic impairment
   • Taking concurrently with monoamine oxidase inhibitors (MAOIs) or reserpine
   • Taking concurrently with other VMAT2 inhibitors

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

6. Is the treatment being prescribed by, or in consult with, a psychiatrist?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member demonstrate a positive clinical response to therapy as defined by a decrease in chorea causing functional impairment OR an improvement in AIMS score of 2 or more points or improvement in ESRI score of 4 or more points compared to baseline? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

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

Note:
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References:


## Affected Medication(s)
- Xermelo oral tablet

## FDA Approved Indication(s)
- For the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy

## Dosing
- 250 mg three times daily

## Initial Authorization Criteria

1. Is the request for continuation of Xermelo (telotristat) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have at least a 1-month trial with insufficient response to a somatostatin analog (SSA) (i.e. octreotide, lanreotide) at the maximum indicated dose? (Provide documentation of relevant past medication history and insufficient response)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is Xermelo (telotristat) being prescribed in combination with a somatostatin analog (SSA)? (Provide documentation of treatment regimen)
   a. If yes, approve for 4 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 documentation of diagnosis)
   a. If yes, continue to #3
   b. If no, clinical review required

2. Does the member demonstrate a positive clinical response to therapy defined as a reduction in bowel movement frequency or a reduction in urinary 5-hydroxyindoleacetic acid (5-HIAA) levels? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Is Xermelo (telotristat) being prescribed in combination with a somatostatin analog (SSA) unless an intolerance or contraindication is present? (Provide documentation of treatment regimen)
   a. If yes, approve for 4 months unless otherwise specified
   b. If no, clinical review required

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References:
**Affected Medication(s)**
- Xifaxan oral tablet

**FDA Approved Indication(s)**
- For the treatment of travelers’ diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adults and pediatric patients 12 years of age and older
- For reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults
- For the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults

**Dosing**
- Travelers’ diarrhea: 200mg by mouth three times daily for 3 days
- Hepatic encephalopathy: 550mg by mouth twice daily
- Irritable bowel syndrome with diarrhea: 550mg by mouth three times daily for 14 days

**Initial Authorization Criteria**

1. Is the request for continuation of Xifaxan (rifaximin) therapy for treatment of hepatic encephalopathy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. What is the diagnosis that Xifaxan is being prescribed for?
   a. Travelers’ diarrhea, continue to corresponding criteria
   b. Hepatic encephalopathy, continue to corresponding criteria
   c. Irritable bowel syndrome with diarrhea, continue to corresponding criteria

**Travelers’ diarrhea**

1. Is the member 12 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, contraindication, or intolerance to one of the following fluoroquinolone regimens for the treatment of travelers’ diarrhea? (Provide relevant past medication history or documentation of contraindication/intolerance)
   - Ciprofloxacin 500 mg twice daily for 1-3 days
   - Levofloxacin 500 mg once daily for 1-3 days
   - Ofloxacin 200 mg twice daily for 1-3 days
   a. If yes, continue to #3
b. If no, clinical review required

3. Does the member have a trial with insufficient response, intolerance, or contraindication to azithromycin 1000mg as a single dose for the treatment of travelers’ diarrhea? (Provide relevant past medication history or documentation of contraindication/intolerance)
   a. If yes, approve for 3 days
   b. If no, clinical review required

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 relevant past medication history)
   a. If yes, continue to #3
   b. If no, continue to #4

3. Will the member continue to take lactulose concurrently with Xifaxan?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

4. Does the member have an intolerance or contraindication to lactulose? (Provide documentation of contraindication/intolerance)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have altered mental status?
   a. If yes, approve for 6 months unless otherwise specified
   b. If no, clinical review required

Irritable bowel syndrome with diarrhea

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, intolerance, or contraindication to loperamide at the maximal indicated dose? (Provide relevant past medication history or documentation of contraindication/intolerance)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a trial with insufficient response, intolerance, or contraindication to an antispasmodic agent at the maximal indicated dose? (i.e. dicyclomine) (Provide relevant past medication history or documentation of contraindication/intolerance)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Has the member had 3 or more previous Xifaxan (rifaximin) treatment courses for irritable bowel syndrome with diarrhea? (Provide relevant past medication history)
   a. If yes, clinical review required
   b. If no, approve for 14 days

Reauthorization Criteria

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

2. Is Xifaxan (rifaximin) being used concurrently with lactulose unless a contraindication or intolerance is present? (Provide current treatment regimen or documentation of contraindication/intolerance)
   a. If yes, continue to #3
   b. If no, clinical review required

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

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References:


# Xolair® (omalizumab)
## Prior Authorization Guidelines

### Affected Medication(s)
- Xolair subcutaneous solution

### FDA Approved Indication(s)
- For patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids
- For the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment

### Dosing
- Reference dosing recommendations in package insert

### Initial Authorization Criteria

1. Is the request for continuation of Xolair (omalizumab) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Which diagnosis is Xolair (omalizumab) being requested for?
   a. Moderate to severe persistent asthma, continue to corresponding criteria
   b. Chronic Idiopathic Urticaria (CIU), continue to corresponding criteria

#### Moderate to severe persistent asthma

1. Is the member at least 6 years of age?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member currently on a high-dose inhaled corticosteroid (ICS)?
   a. If yes, continue to #4
   b. If no, clinical review required

3. Is the member on a long acting beta agonist (LABA)?
   a. If yes, continue to #5
   b. If no, continue to #4
4. Does the member have a history of intolerance or contraindication to LABA and is on a leukotriene modifier (LTRA)?
   a. If yes, continue to #5
   b. If no, clinical review required

5. Has the member experienced 2 or more exacerbations within the last 12 months that required systemic steroid treatment, an urgent care visit, or hospitalization despite adherence to asthma maintenance therapy? (Provide documentation of exacerbation history)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the member have a baseline immunoglobulin E (IgE) level between 30 and 700 IU/mL? (Provide baseline IgE lab results)
   a. If yes, continue to #7
   b. If no, clinical review required

7. Does the member have body weight less than 150 kg?
   a. If yes, continue to #8
   b. If no, clinical review required

8. Does the member have a positive skin test or in vitro reactivity to a perennial aeroallergen? (Provide allergen test results)
   a. If yes, continue to #9
   b. If no, clinical review required

9. Is Xolair (omalizumab) prescribed in combination with current asthma treatment regimen? (Provide documentation of planned treatment regimen)
   a. If yes, continue to #10
   b. If no, clinical review required

10. Is Xolair (omalizumab) prescribed by, or in consult with an allergist or pulmonologist?
    a. If yes, approve for 6 months unless otherwise specified
    b. If no, clinical review required

Chronic Idiopathic Urticaria (CIU)

1. Is the member 12 years of age or older?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Does the member have a history of trial with insufficient response, intolerance, or contraindication to TWO antihistamines at maximum indicated doses for a duration of at least 2 weeks? (Provide documentation of past medications used along with response to therapy)
   a. If yes, continue to #3
   b. If no, clinical review required
3. Does the member have a history of trial with insufficient response, intolerance, or contraindication to a leukotriene modifier (LTRA) in combination with an antihistamine at maximum indicated doses for a duration of at least 2 weeks? (Provide documentation of past medications used along with response to therapy)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is Xolair (omalizumab) prescribed by, or in consult with an allergist or dermatologist?
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Which diagnosis is Xolair (omalizumab) being requested for?
   a. Moderate to severe persistent asthma, please see corresponding criteria
   b. Chronic Idiopathic Urticaria (CIU), please see corresponding criteria

Moderate to severe persistent asthma

1. Is the member adherent to asthma maintenance therapy defined as a high-dose ICS plus a LABA or LTRA?
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the member responding positively to therapy defined as reduction in exacerbations, reductions in corticosteroid dose, or improvement in FEV1 compared to baseline? (Provide supporting documentation)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Is Xolair (omalizumab) prescribed by, or in consult with an allergist or pulmonologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

Chronic Idiopathic Urticaria (CIU)

1. Is the member responding positively to therapy defined as reduction in symptoms compared to baseline? (Provide supporting documentation)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is Xolair (omalizumab) prescribed by, or in consult with an allergist or dermatologist?
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required
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References:
# Xyrem® (sodium oxybate)
## Prior Authorization Guidelines

### Affected Medication(s)
- Xyrem oral solution

### FDA Approved Indication(s)
- For the treatment of cataplexy in narcolepsy
- For the treatment of excessive daytime sleepiness (EDS) in narcolepsy

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

### Initial Authorization Criteria

1. Is the request for continuation of Xyrem (sodium oxybate) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

2. Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)
   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. Is the medication prescribed by, or in consult with, a neurologist or a sleep specialist?
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have a confirmed diagnosis of narcolepsy as defined by a multiple sleep latency test showing mean onset to sleep less than 10 minutes? (Provide sleep study results for review)
   a. If yes, continue to #6
   b. If no, clinical review required

6. Does the member have any of the following contraindications to Xyrem (sodium oxybate)?
   - Concurrent treatment with sedative hypnotic agents
   - Alcohol consumption
   - Semialdehyde dehydrogenase deficiency
     a. If yes, clinical review required
     b. If no, continue to #7

7. What is the diagnosis Xyrem (sodium oxybate) is being prescribed for?
   a. Narcolepsy with cataplexy, continue to corresponding criterion
b. Narcolepsy with excessive daytime sleepiness (EDS), continue to corresponding criteria

Narcolepsy with cataplexy

1. Does the member have a minimum of a one-month trial with insufficient response, intolerance, or contraindication to TWO of the following therapy categories? (Provide past medication history)
   - Atomoxetine
   - SSRI or SNRI (ex. venlafaxine, fluoxetine)
   - Tricyclic antidepressants (ex. clomipramine, protriptyline)

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

Narcolepsy with Excessive daytime sleepiness (EDS)

1. Does the member have a minimum of a one-month trial with insufficient response, intolerance, or contraindication to one of the following stimulants up to maximum the indicated dose? (Provide past medication history)
   - Amphetamine IR
   - Amphetamine/dextroamphetamine IR
   - Dextroamphetamine
   - Methylphenidate IR
   - Matadate ER

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

2. Does the member have a minimum of a one-month trial with insufficient response, intolerance, or contraindication to armodafinil or modafinil up to the maximum indicated dose? (Provide past medication history)

   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required

2. Is the medication prescribed by, or in consult with, a neurologist or sleep specialist physician?
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member demonstrate a positive clinical response to therapy as defined by a reduction in frequency of cataplexy attacks or daytime improvements in wakefulness? (Provide supporting documentation)
   a. If yes, approve for 12 months unless otherwise specified
b. If no, clinical review required

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**References:**


Zelapar® (selegiline hydrochloride)
Prior Authorization Guidelines

Affected Medication(s)
- Zelapar oral disintegrating tablet

FDA Approved Indication(s)
- As an adjunct in the management of patients with Parkinson’s disease being treated with levodopa/carbidopa who exhibit deterioration in the quality of their response to this therapy

Dosing
- Initially, 1.25 mg once daily for at least 6 weeks
- May increase dose to 2.5 mg once daily after initial 6 weeks

Initial Authorization Criteria
1. Is the request for continuation of Zelapar (selegiline hydrochloride) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Is the member currently on levodopa/carbidopa therapy that will be continued concurrently with requested medication? (Provide relevant medication history and treatment plan)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Is the member experiencing a deterioration in the quality of their clinical response to levodopa/carbidopa? (Provide supporting documentation of a decline in response to levodopa/carbidopa demonstrated by at least 3 hours of “off” time per day)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have a trial with inadequate response to, or rationale for avoiding therapy with, the generic selegiline oral tablet? (Provide supporting documentation of trial with inadequate response)
   a. If yes, approve for 6 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the member currently on levodopa/carbidopa therapy that will be continued concurrently with requested medication? (Provide relevant medication history and treatment plan)
   a. If yes, continue to #3
   b. If no, clinical review required

3. Does the member have a positive clinical response to therapy as defined by a decrease in frequency or duration of “off” episodes? (Provide supporting documentation of a decrease in frequency or duration of off episodes)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

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References:
**Zontivity® (vorapaxar)**  
**Prior Authorization Guidelines**

### Affected Medication(s)

- Zontivity oral tablet

### FDA Approved Indication(s)

- Reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). ZONTIVITY has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization.

### Dosing

- 2.08 mg orally once daily

### Initial Authorization Criteria

1. Is the request for continuation of Zontivity (vorapaxar) therapy?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have documentation of a previous myocardial infarction or with current peripheral artery disease? (Provide relevant medical history)
   a. If yes, continue to #4
   b. If no, clinical review required

4. Will the member concurrently be taking aspirin and/or clopidogrel with the requested medication or does the member have a contraindication to either medication? (Provide documentation of treatment plan or contraindication)
   a. If yes, continue to #5
   b. If no, clinical review required

5. Does the member have history of a stroke, transient ischemic attack (TIA), or intracranial hemorrhage (ICH)? (Provide supporting documentation)
   a. If yes, clinical review required
   b. If no, continue to #6

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

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<td>Is the request for use to treat an FDA approved indication? (Provide documentation of diagnosis)</td>
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<td>2.</td>
<td>Will the member concurrently be taking aspirin and/or clopidogrel with the requested medication or does the member have a contraindication to either medication? (Provide documentation of treatment plan or contraindication)</td>
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<td>b. If no, clinical review required</td>
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<td>3.</td>
<td>Has the member had a stroke, transient ischemic attack (TIA), or intracranial hemorrhage (ICH) while taking Zontivity?</td>
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<td>a. If yes, clinical review required</td>
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<td>b. If no, continue to #4</td>
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<td>4.</td>
<td>Does the member have an absence of serious adverse reactions from therapy (i.e. bleeding)?</td>
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<td>Is the treatment being prescribed by, or in consultation with, a cardiologist?</td>
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References:

### Affected Medication(s)
- Zurampic oral tablet
- Duzallo oral tablet

### FDA Approved Indication(s)
- **Zurampic**: In combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone
- **Duzallo**: The treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone

### Dosing
- **Zurampic**: 200 mg once daily co-administered with a xanthine oxidase inhibitor
- **Duzallo**: One tablet daily

### Initial Authorization Criteria

1. Is the request for continuation of Zurampic (lesinurad) or Duzallo (lesinurad/allopurinol)?
   a. If yes, continue to Reauthorization
   b. If no, continue to #2

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

3. Does the member have a trial with allopurinol or Uloric (febuxostat) at a maximally tolerated dose with insufficient response? (Provide documentation of trial with insufficient response if applicable)
   a. If, yes, continue to #4
   b. If no, clinical review required

4. Is Zurampic (lesinurad) being requested?
   a. If yes, continue to #5
   b. If no, approve for 12 months unless otherwise specified

5. Will Zurampic (lesinurad) be taken in combination with either allopurinol or Uloric (febuxostat)?
   a. If yes, approve for 12 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 documentation of diagnosis)
   a. If yes, continue to #2
   b. If no, clinical review required
2. Is the medication being requested Zurampic (lesinurad)?
   a. If yes, continue to #3
   b. If no, continue to #4

3. Will Zurampic (lesinurad) be taken in combination with either allopurinol or Uloric (febuxostat)?
   a. If yes, continue to #4
   b. If no, clinical review required

4. Has the member demonstrated a positive clinical response to therapy defined as lower uric acid levels than prior to initiation of therapy? (Provide documentation of decreased uric acid level)
   a. If yes, approve for 12 months unless otherwise specified
   b. If no, clinical review required

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**References:**